

Fig 1

A

Step : 0.050° Cnt Time: 1.000 Sec.
Range: 2.00 - 40.00 (Deg) Cont. Scan Rate : 3.00 Deg/min.

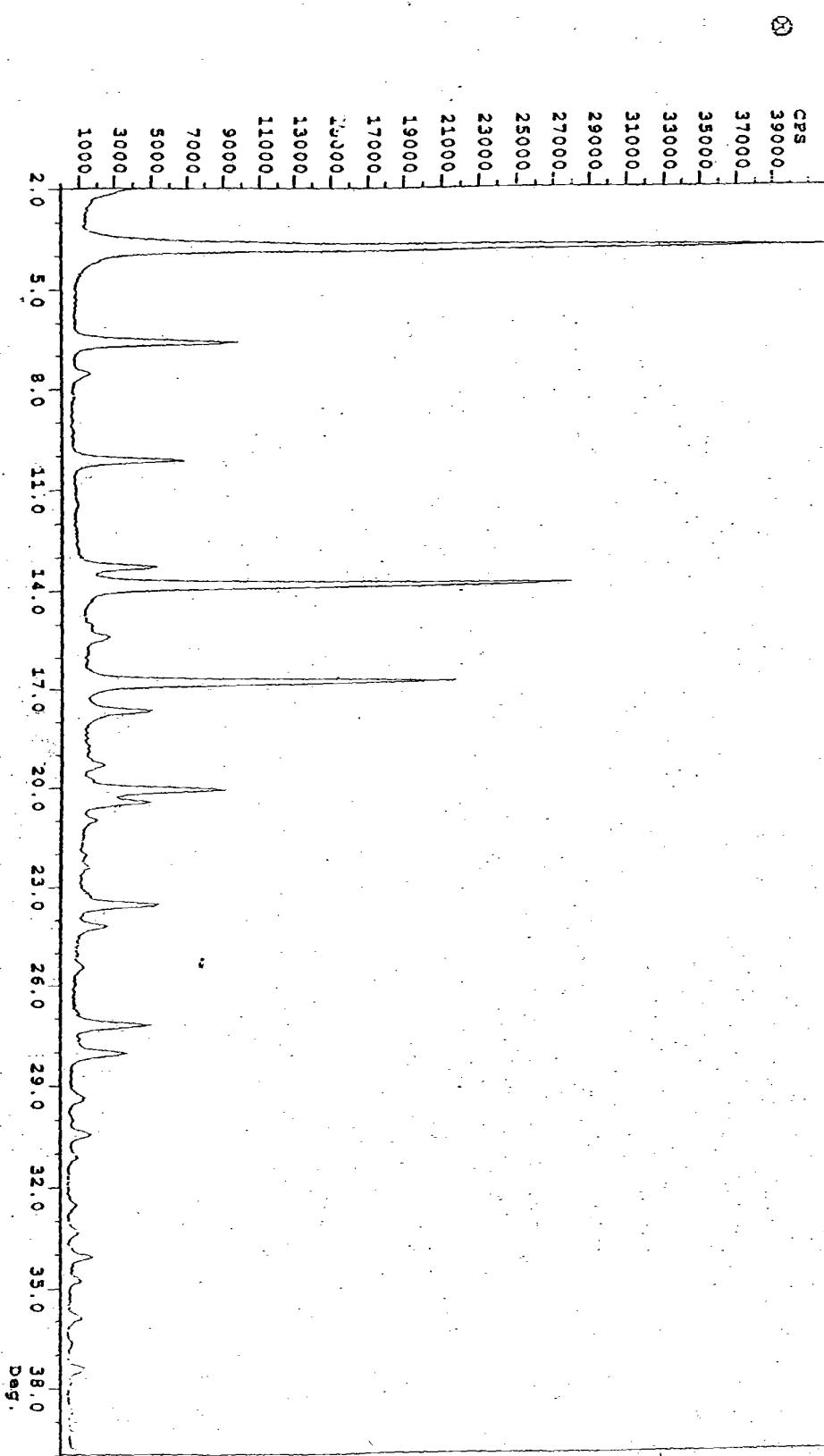


Fig. 2
C

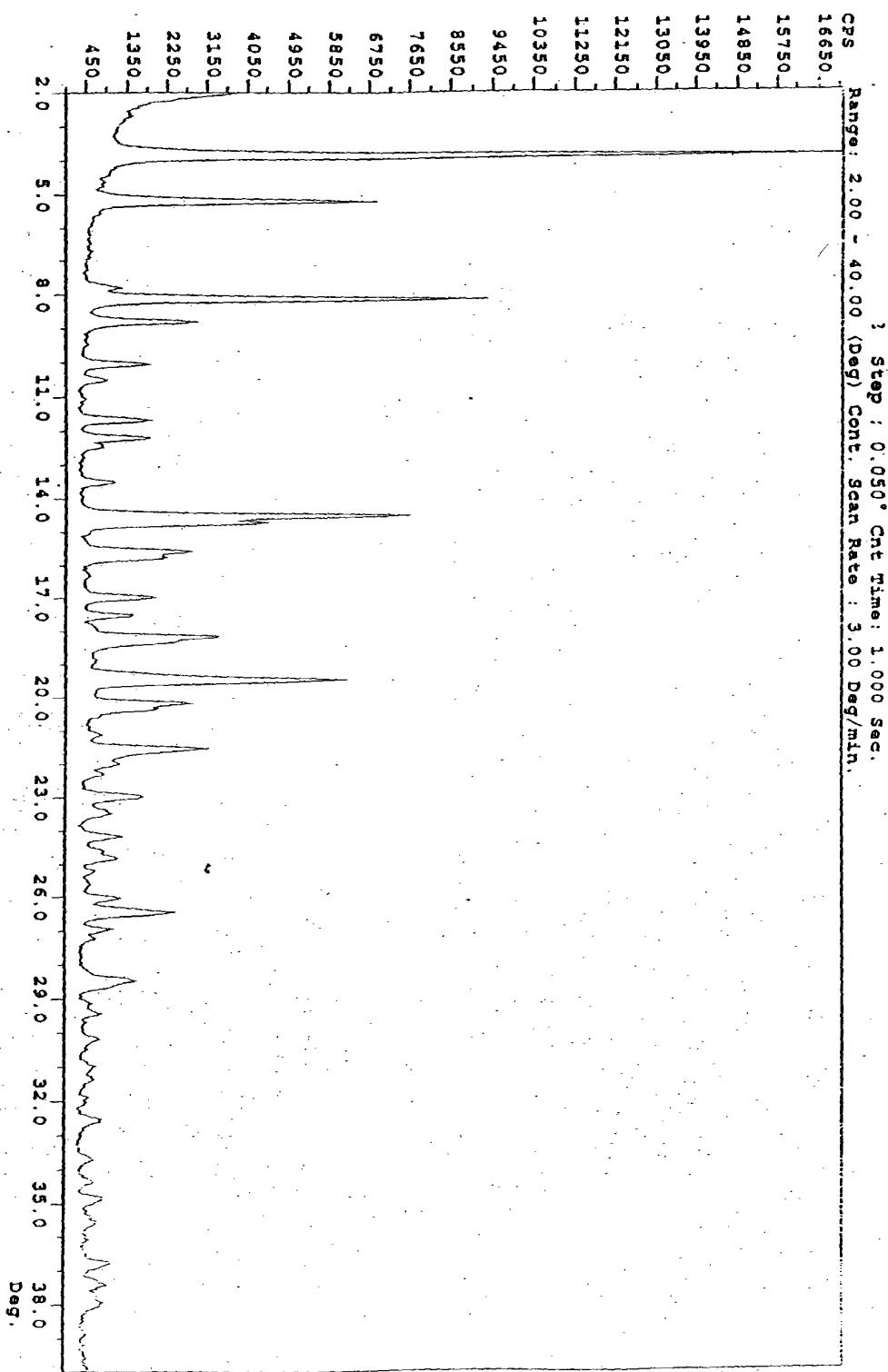


Fig 3 D

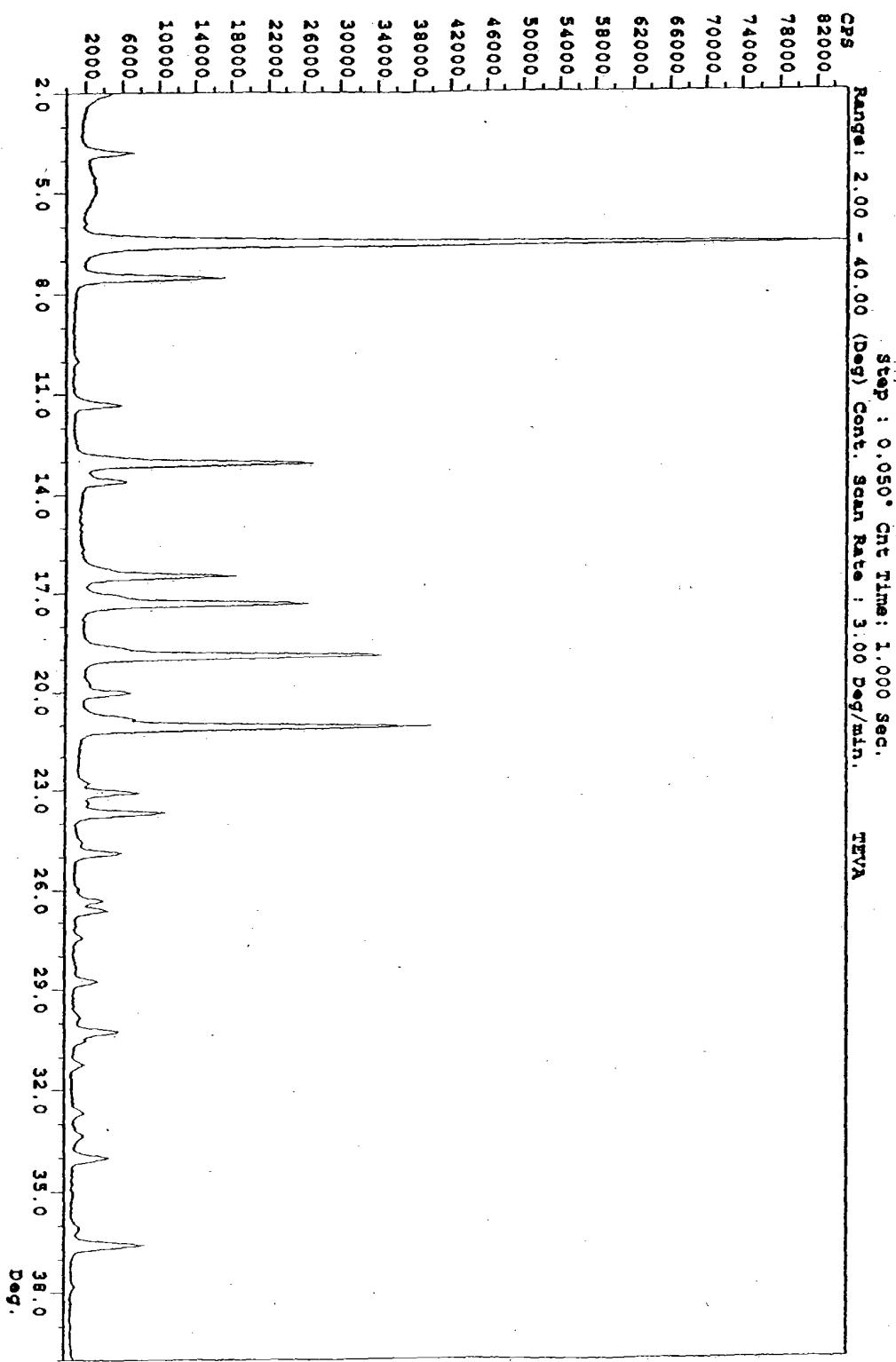


Fig 4 E

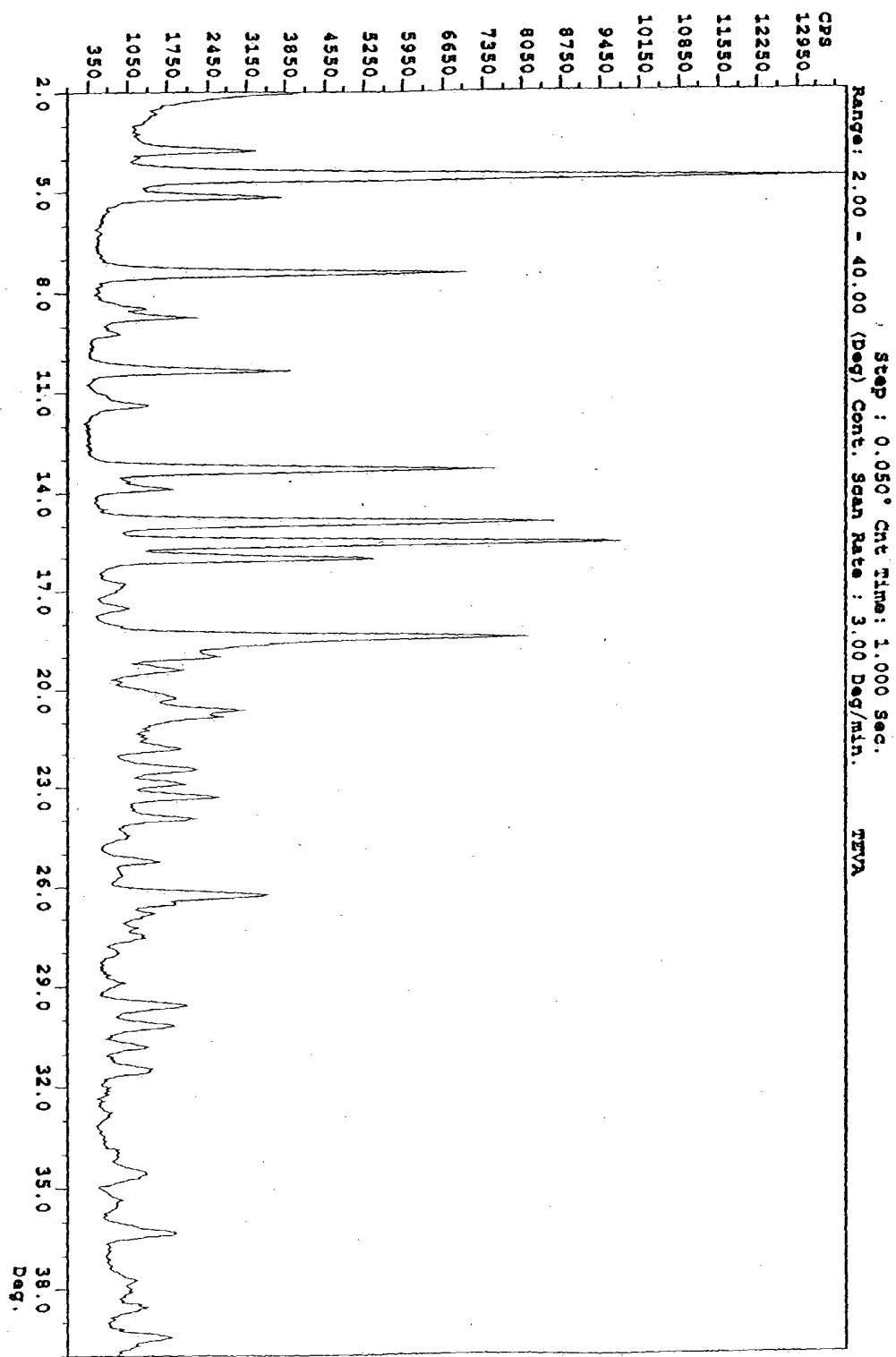


Fig. 5

F

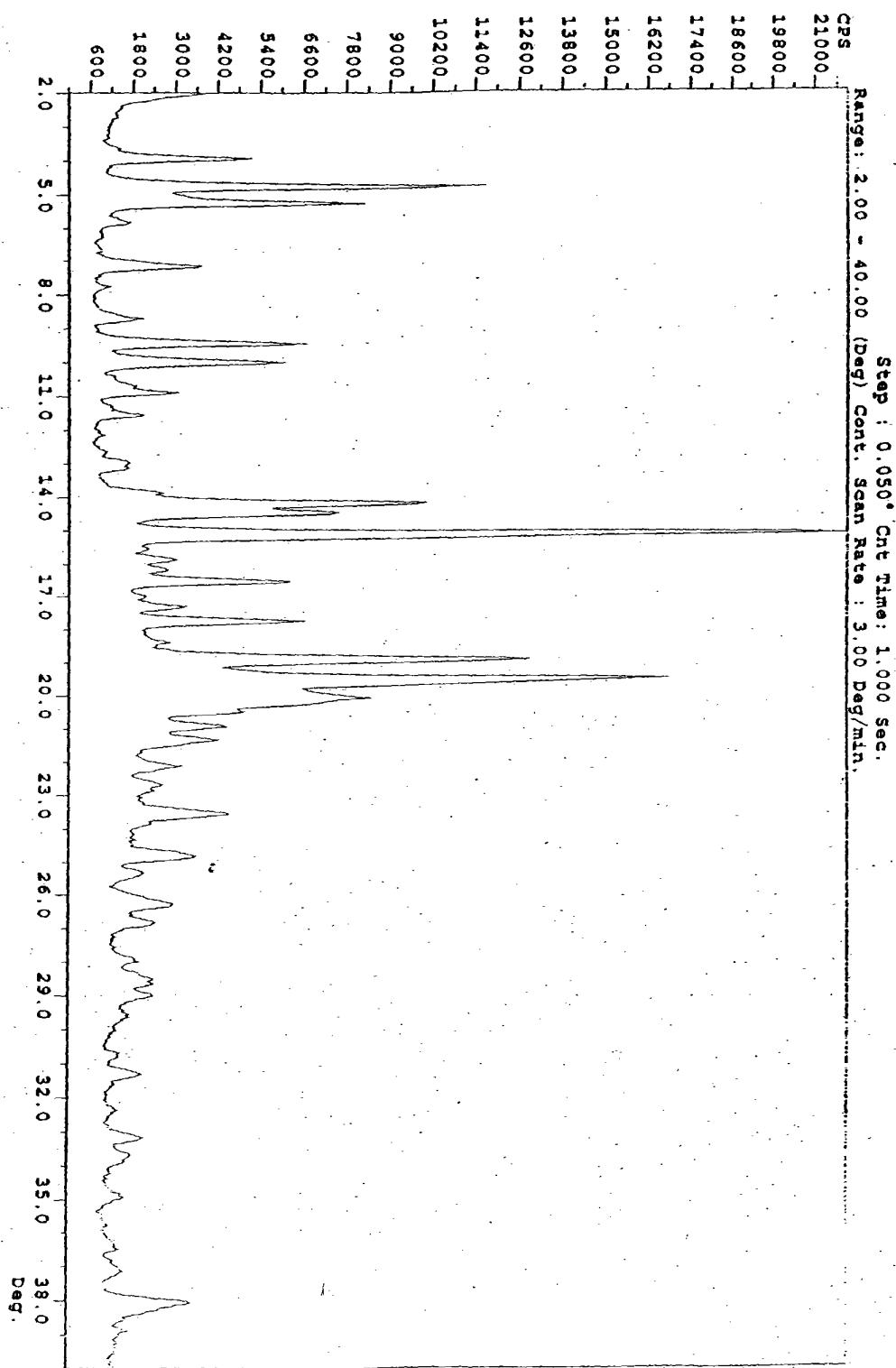
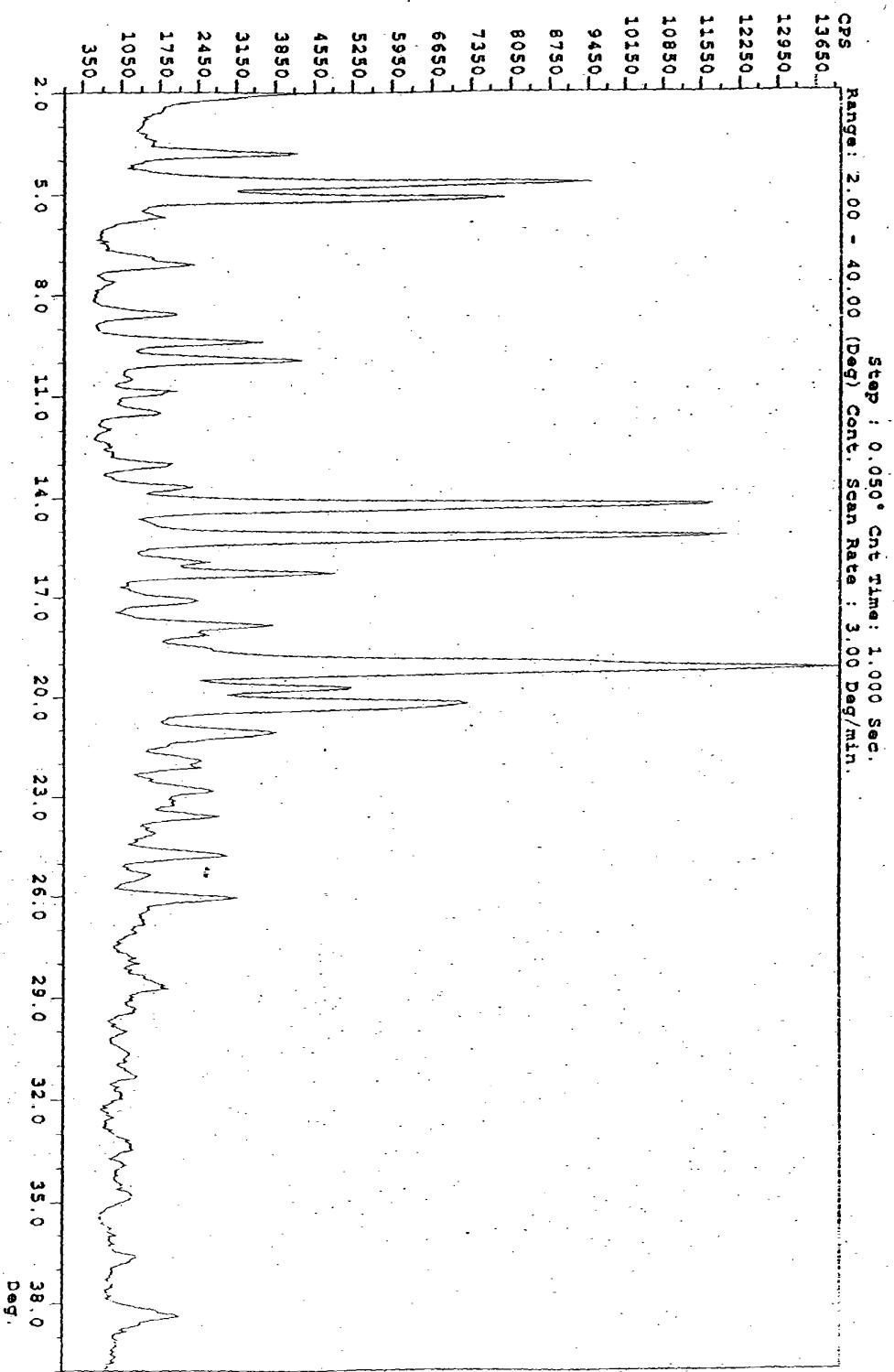


Fig. 6

G



L97 T

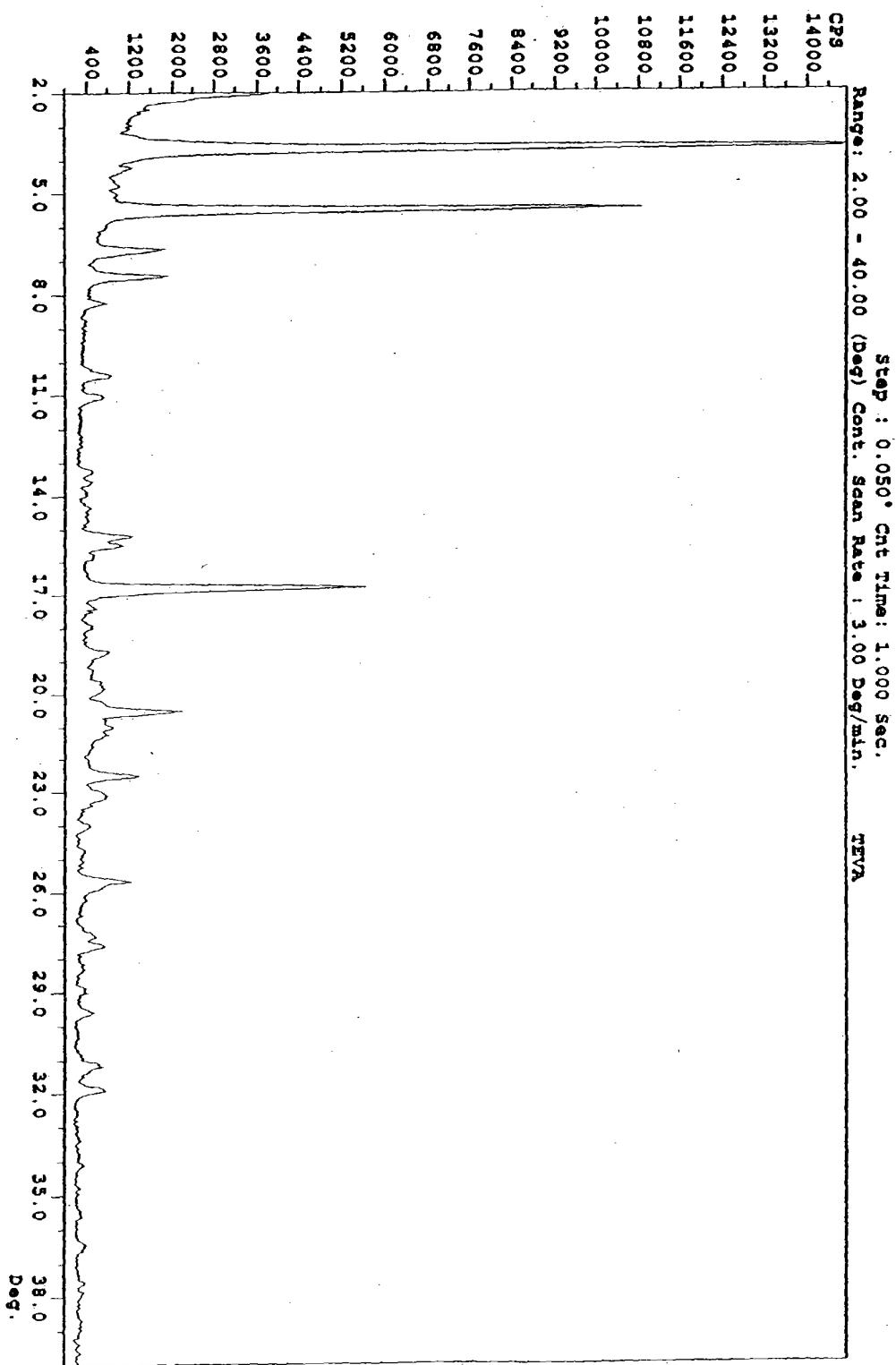


Fig. 8
J

Range: 2.00 - 40.00 (Deg) Step : 0.050° Cnt Time: 1.000 Sec.

Cont. Scan Rate : 3.00 Deg/min.

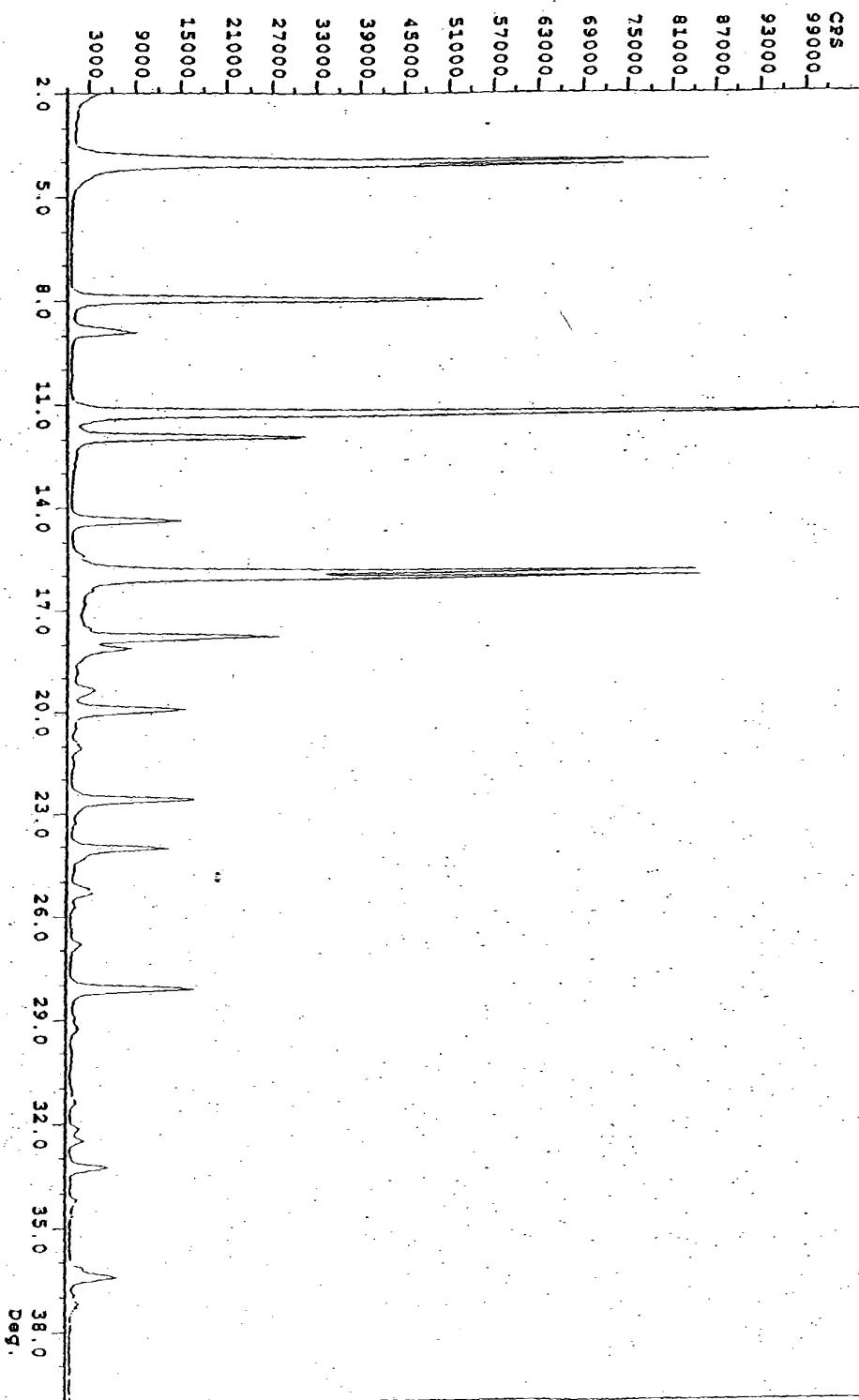


Fig. 9

K

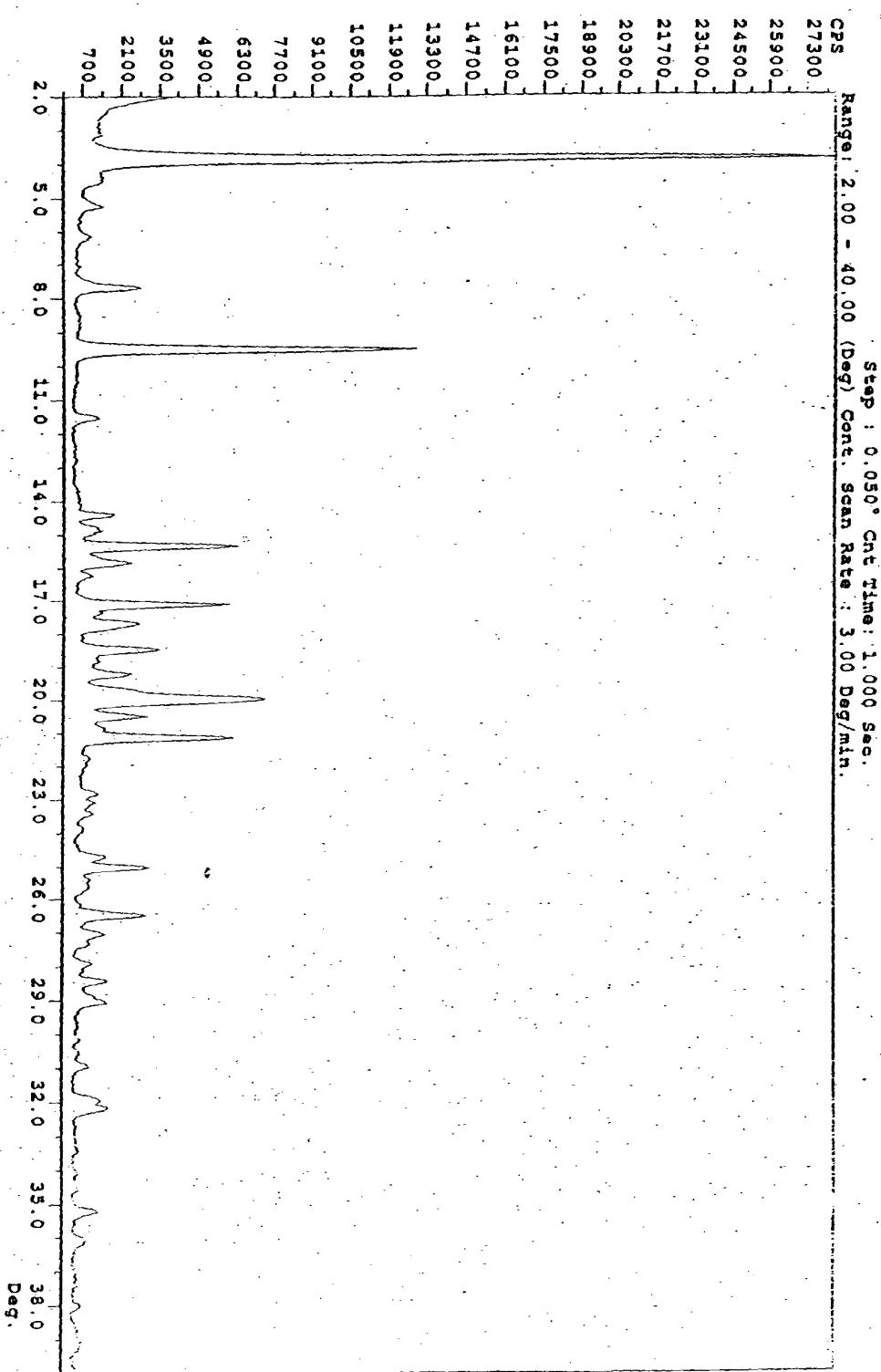


Fig. 10
L

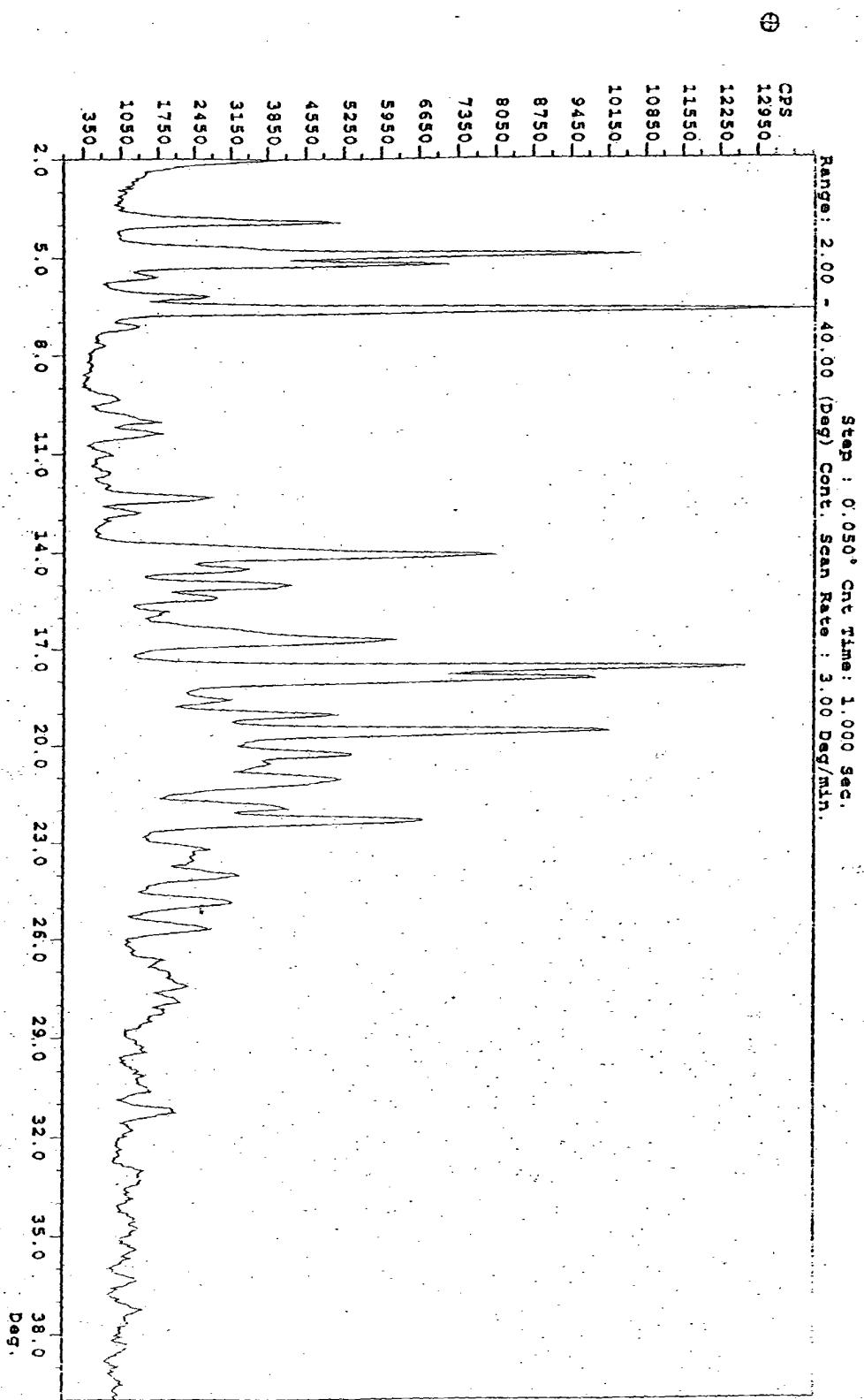
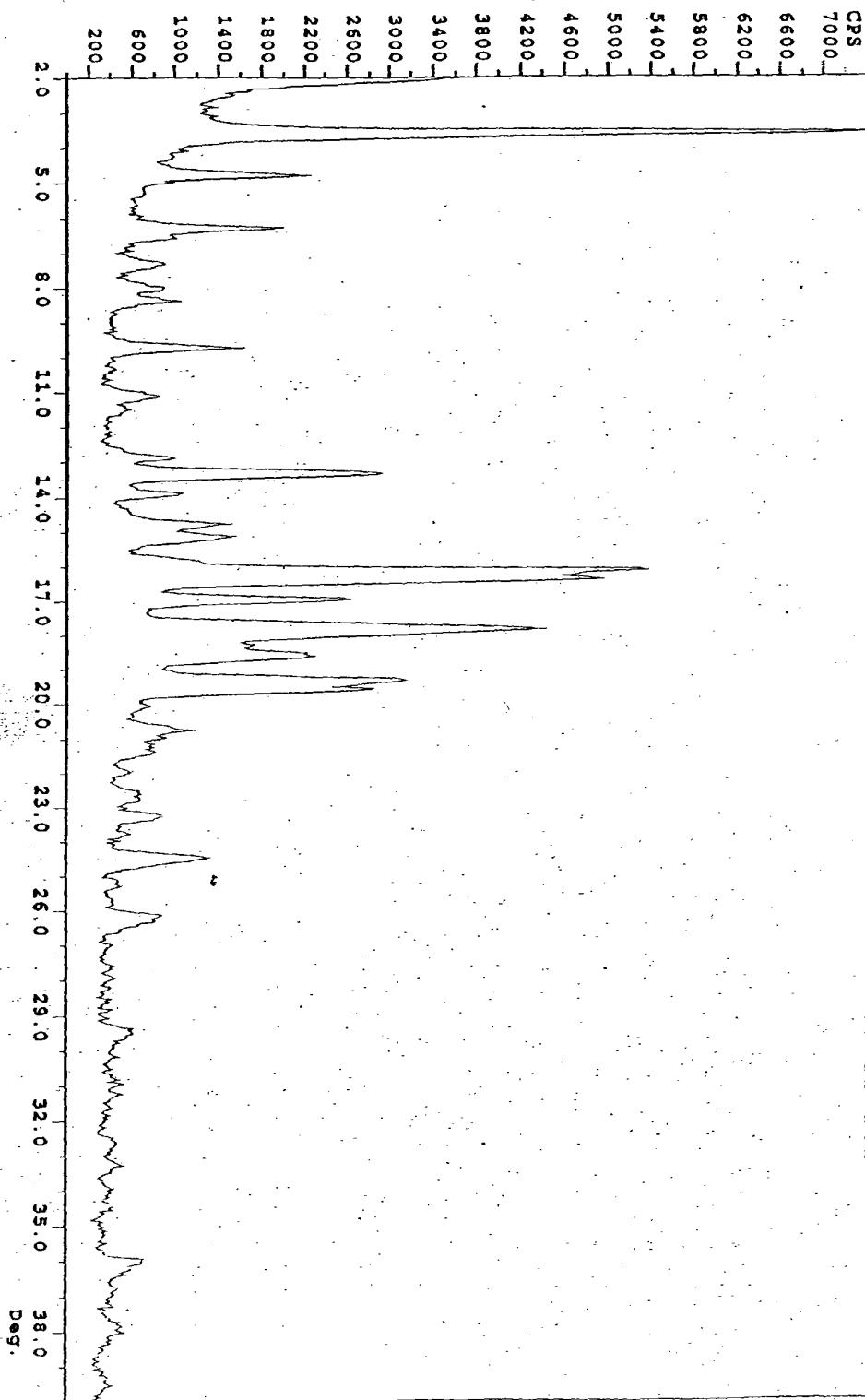


Fig. 11

M

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.

CPS



⊕

Fig. 12

N

Range: 2.00 - 40.00 (Deg) Step : 0.050° Cnt Time: 1.000 sec.
CPS Cont. Scan Rate : 3.00 Deg/min.

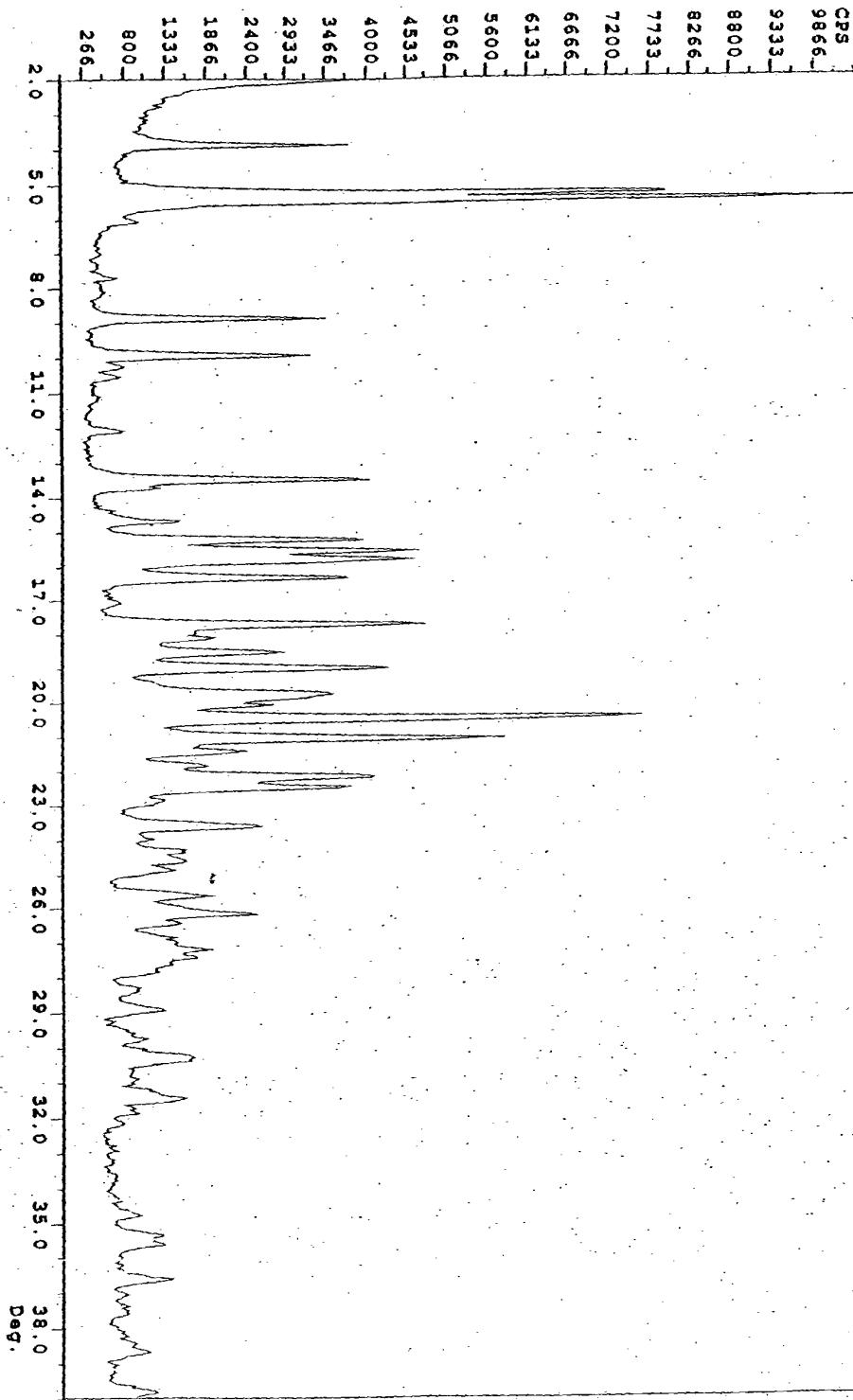
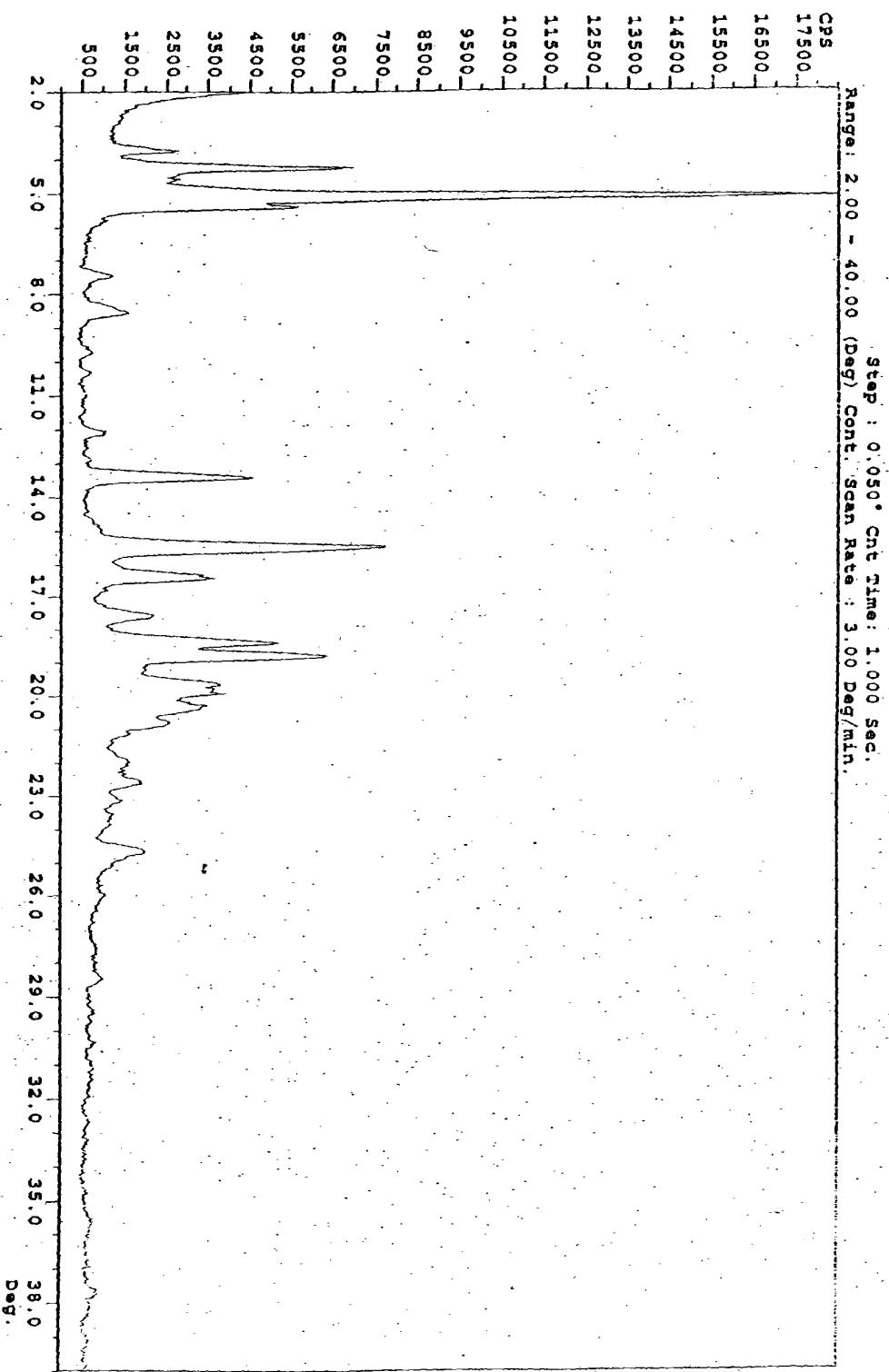


Fig. 13 O

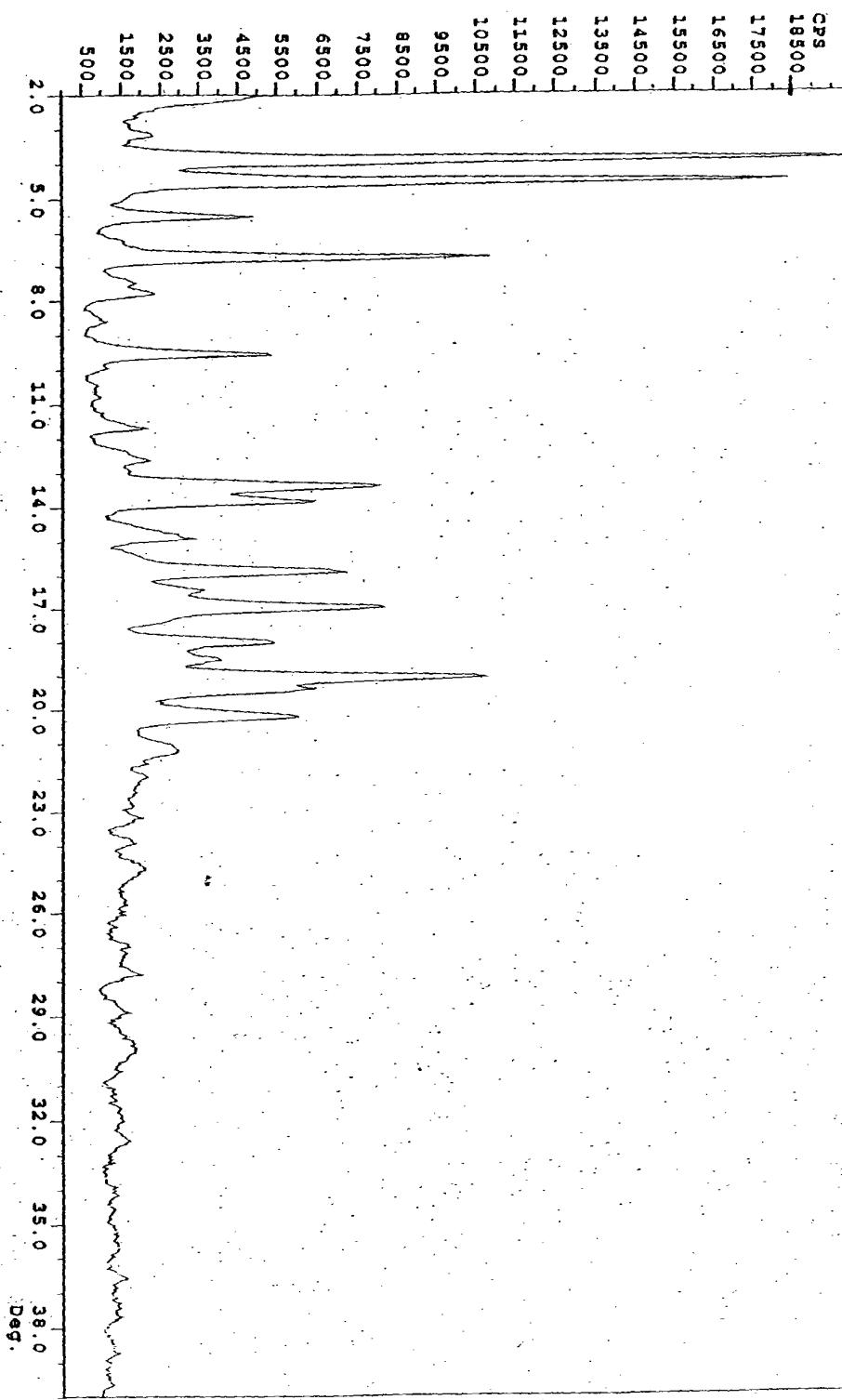


⊗

Fig. 14.

P

Range: 2.00 - 40.00 Step : 0.050° Cnt Time: 1.000 Sec.
Cont. Scan Rate : 3.00 Deg/min.



(2)

F, g, 15

Q

Step : 0.050° Cnt Time: 1.000 Sec.
Range: 2.00 - 40.00 (Deg) Cont. Scan Rate : 3.00 Deg/min.

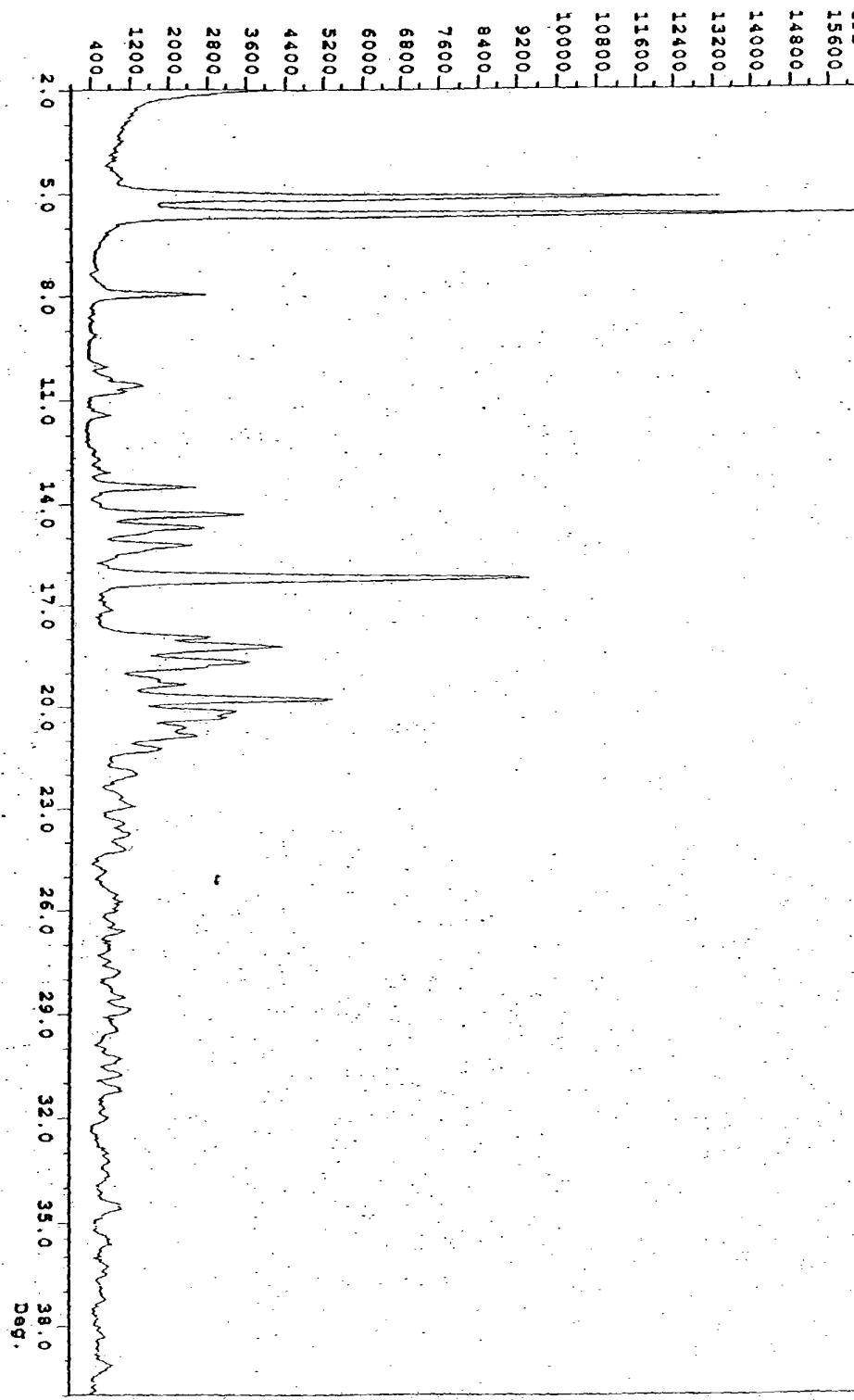
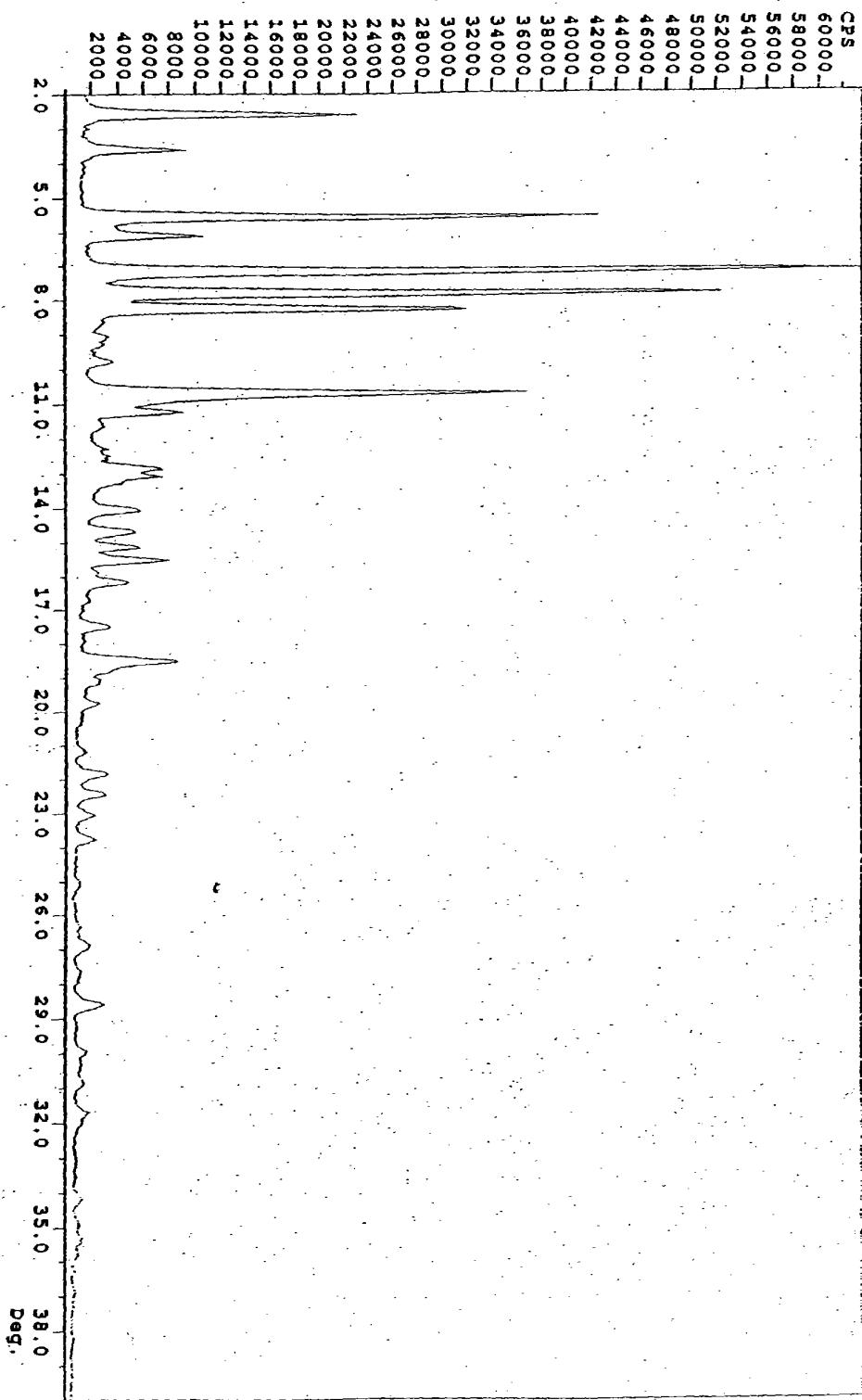


Fig. 16 - T

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.
Step : 0.050° Cont. Scan Rate : 3.00 Deg/min.



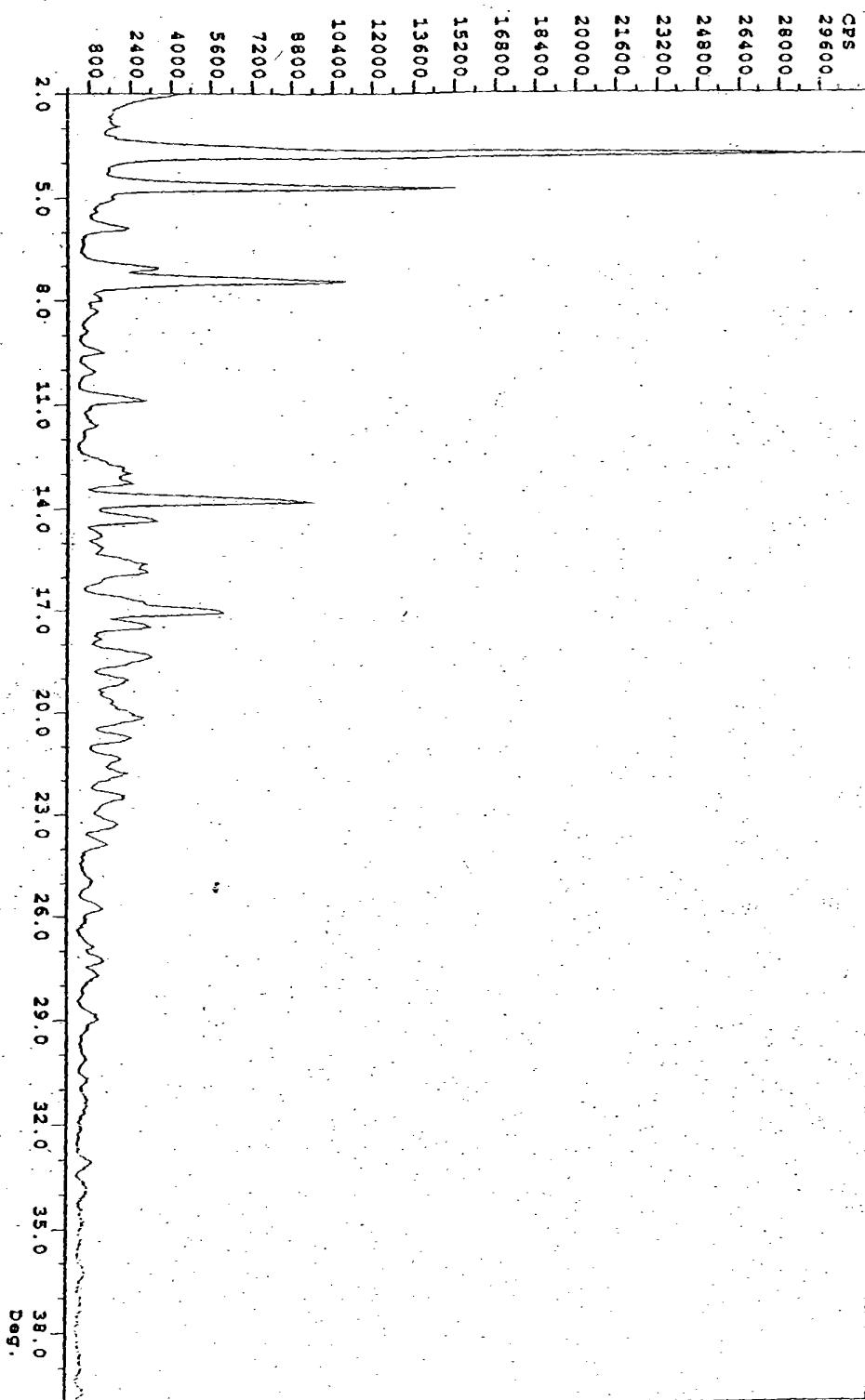
④

Fig. 17

U

Range: 2.00 - 40.00 (Deg) Cont. Scan Rate: 3.00 Deg/min.

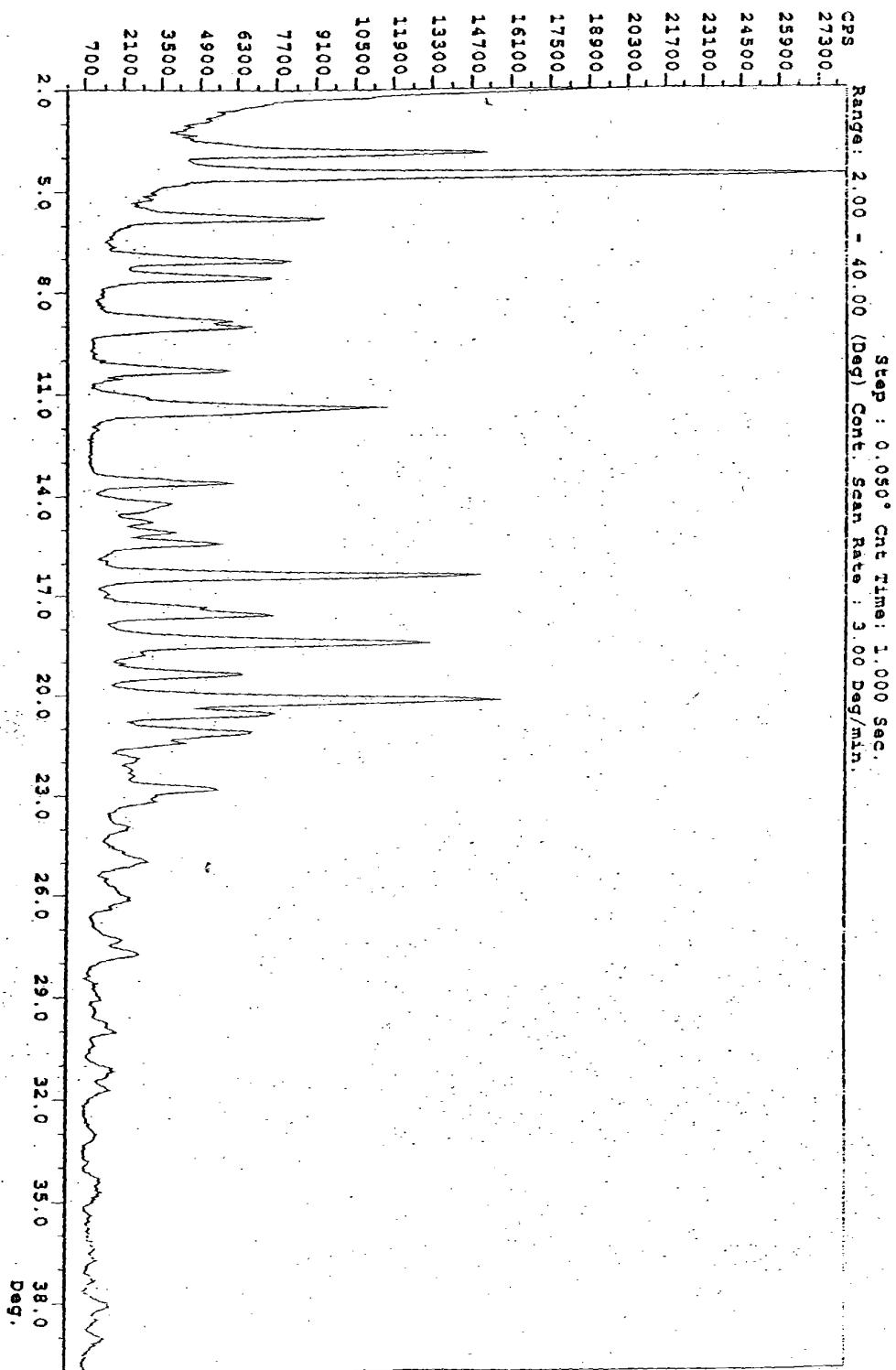
Step: 0.050° Cnt Time: 1.000 sec.



⊕

Fig. 18

✓



⊕

fig 19 r

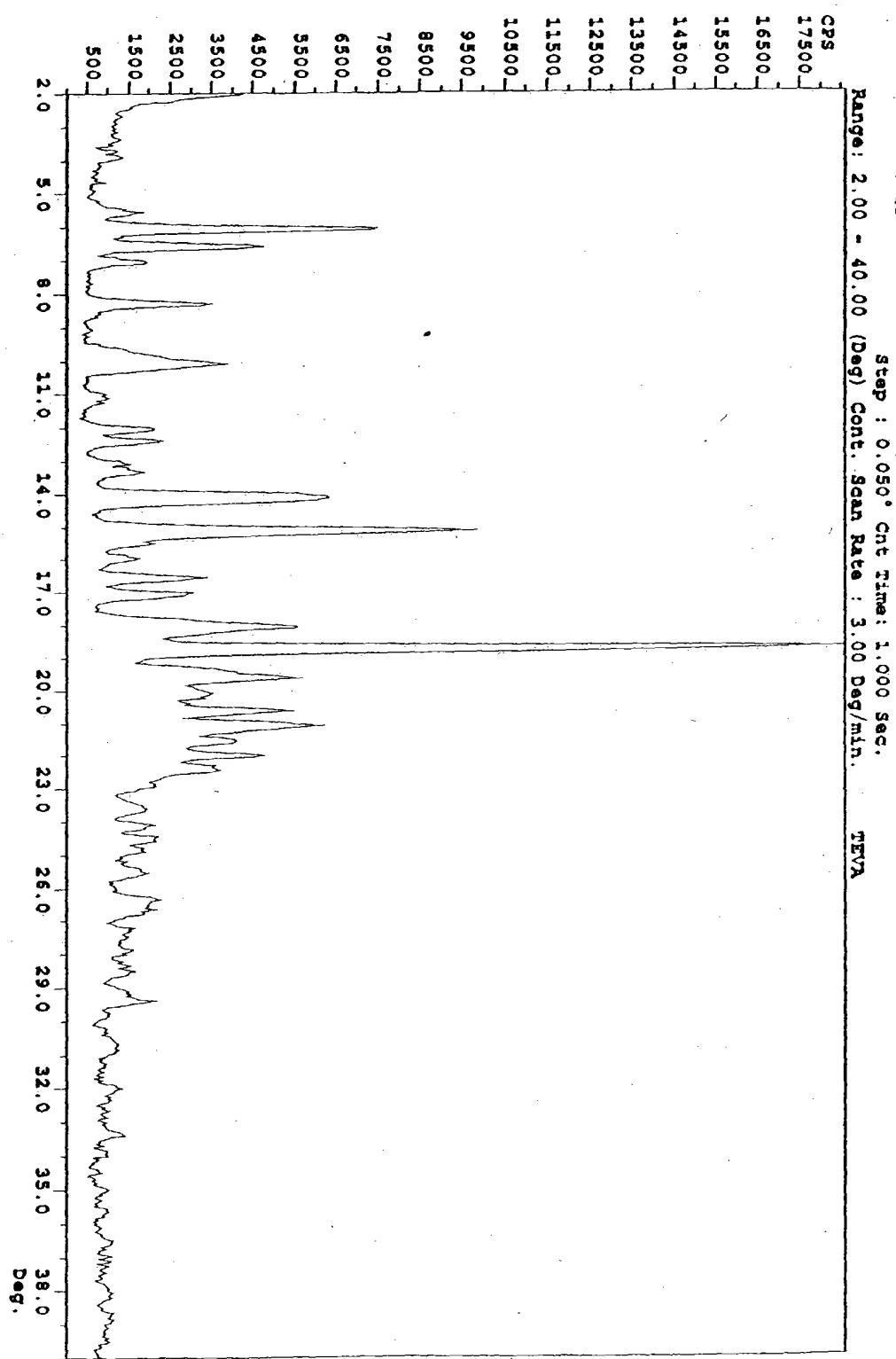


Figure 20 - Natta Linde Form Z

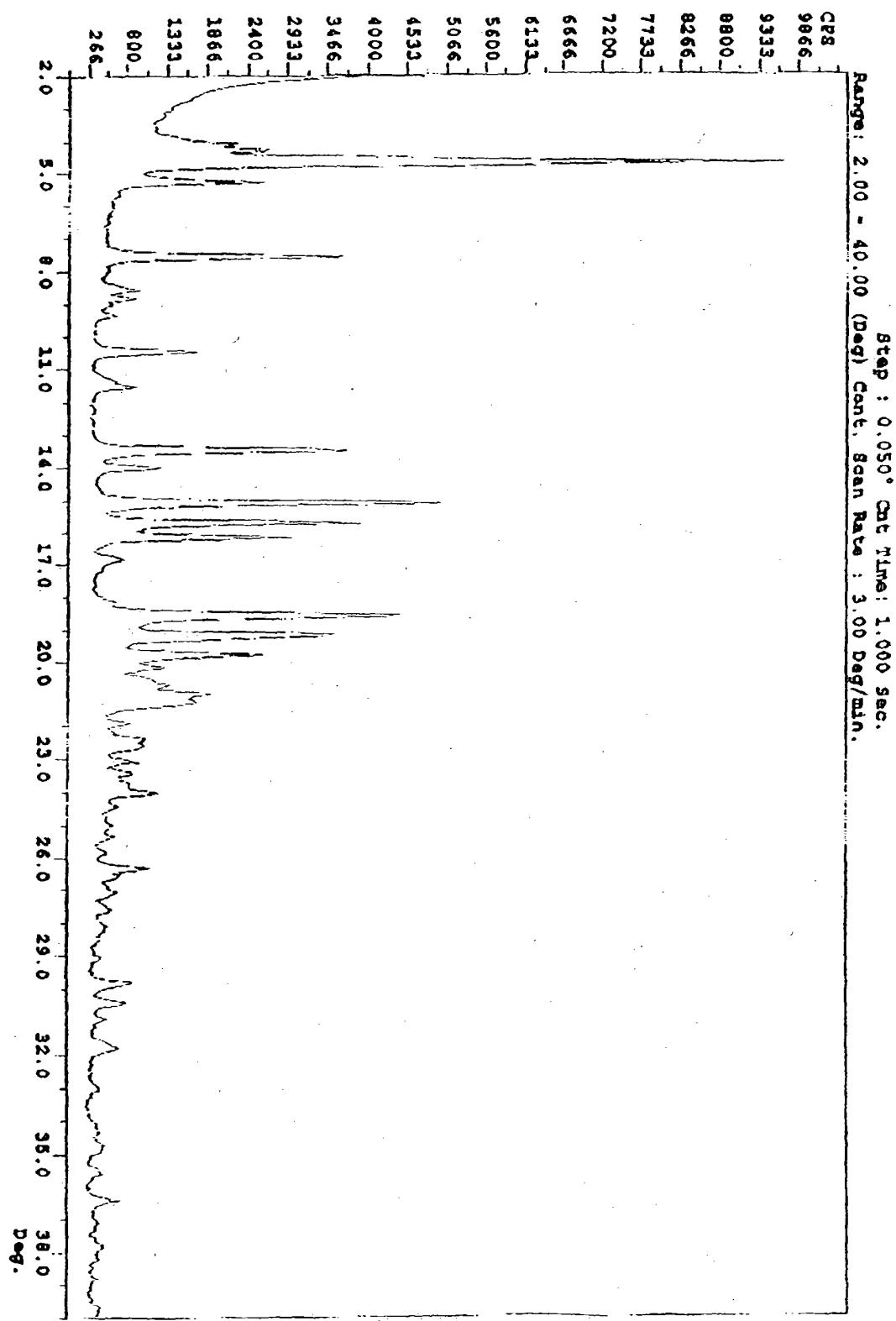


fig 2A

Step : 0.050° Cnt Time: 1.000 sec.
Range: 2.00 - 40.00 (Deg) Cont. Scan Rate : 3.00 Deg/min. TEVA

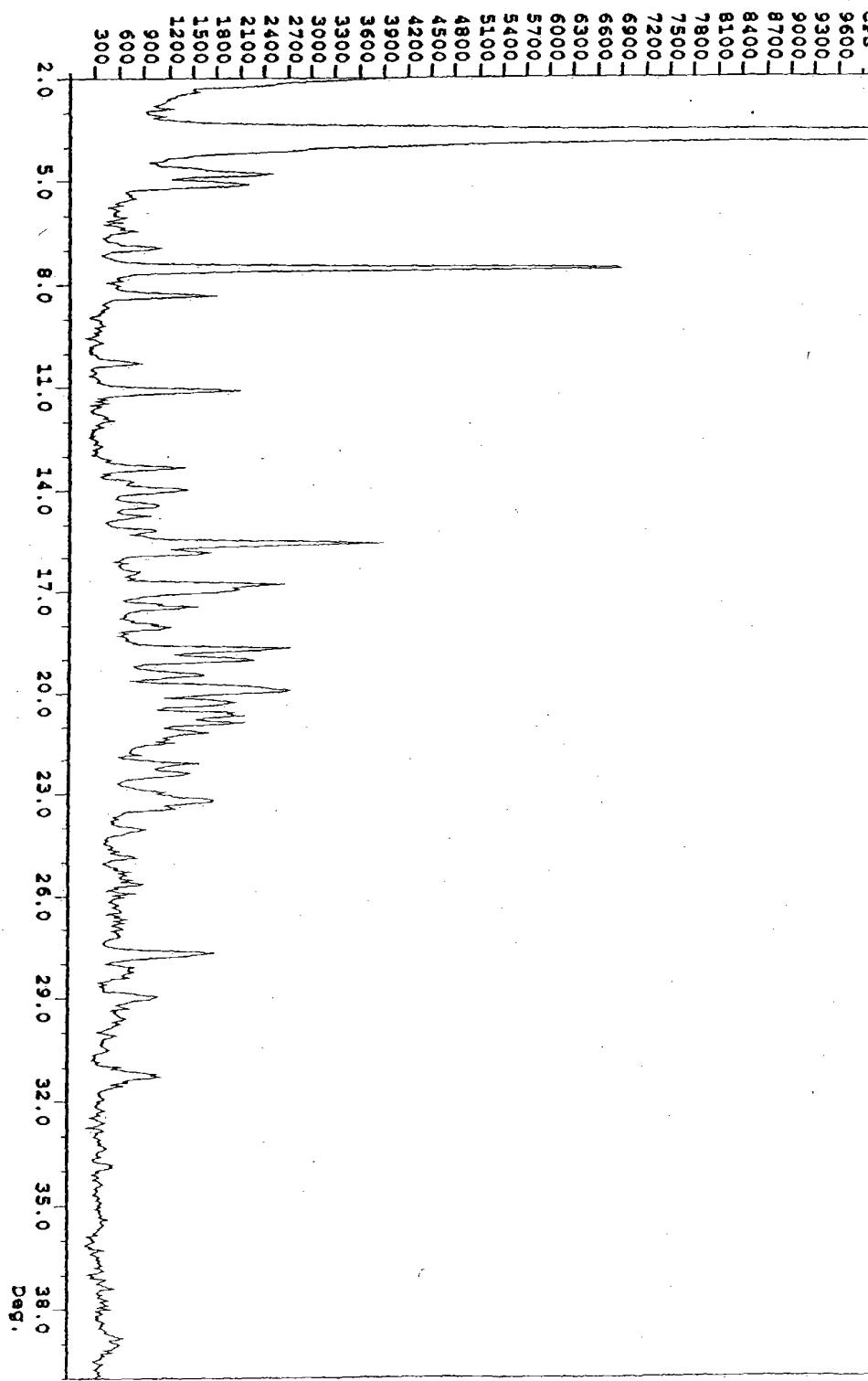


Fig. 2A β

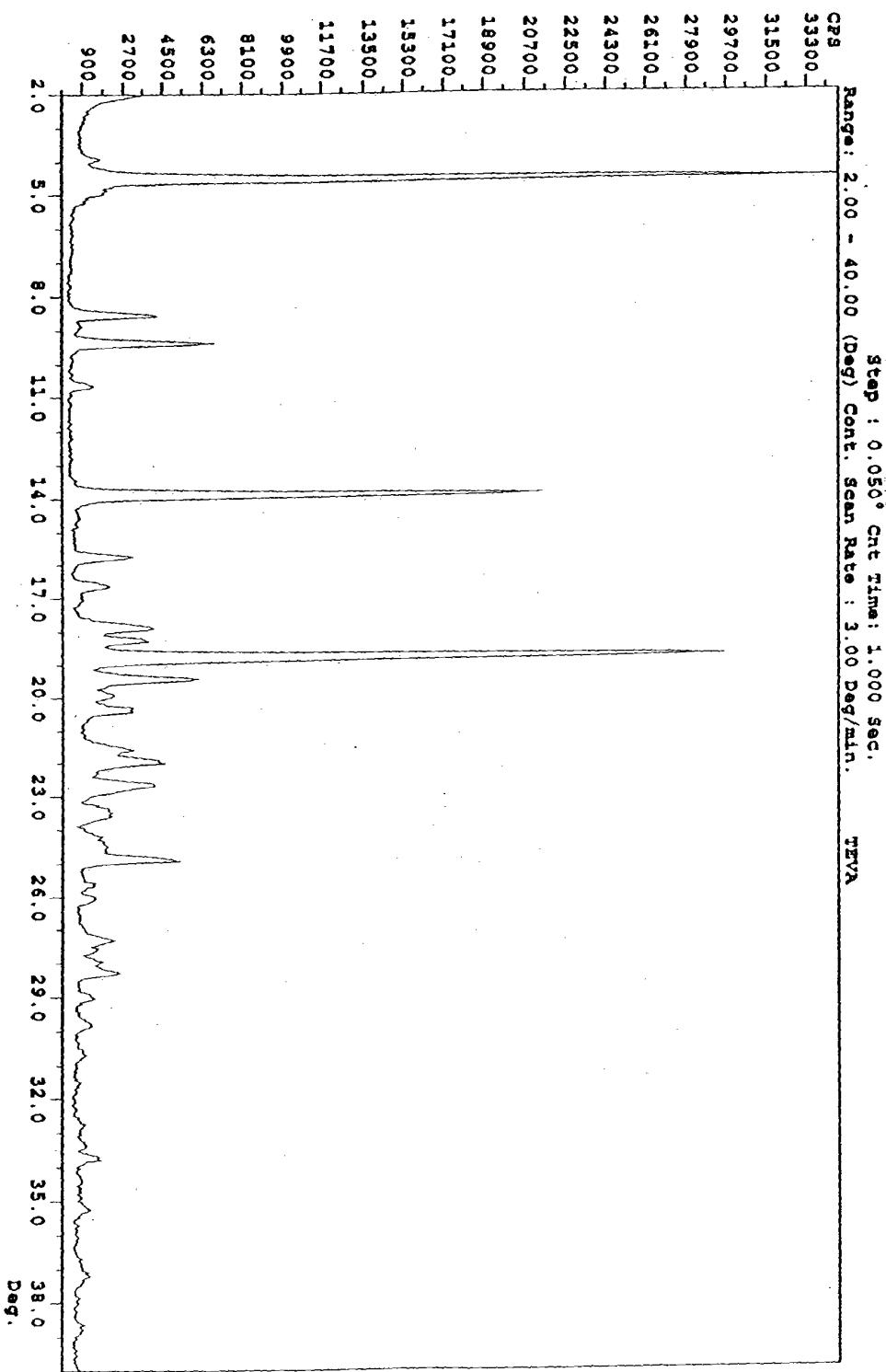


Fig 23

10

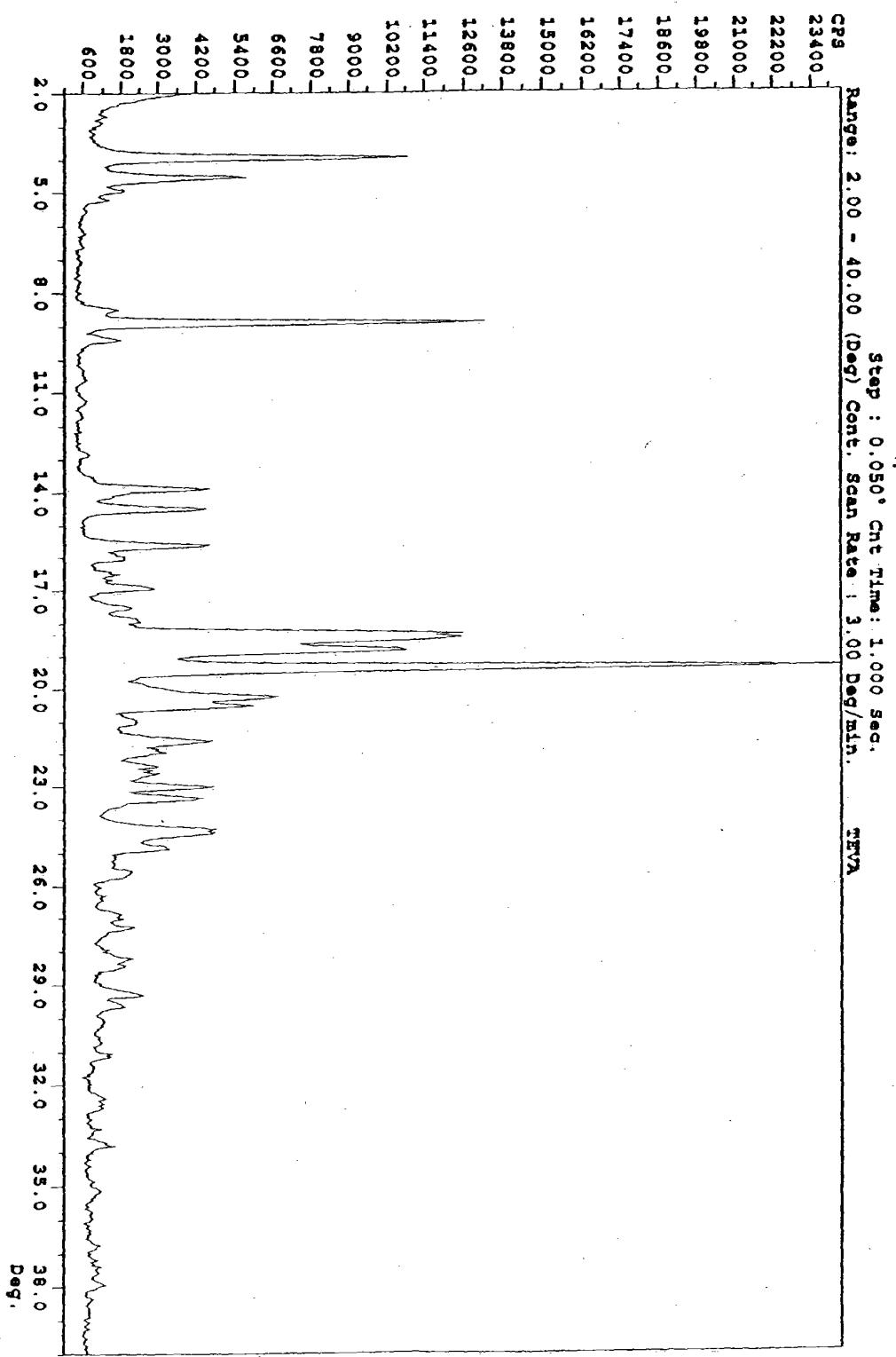


Fig 24

Step : 0.050° Cnt Time: 1.000 sec.
Range: 2.00 - 40.00 (Deg) Cont. Scan Rate: 3.00 Deg/min.

TEN

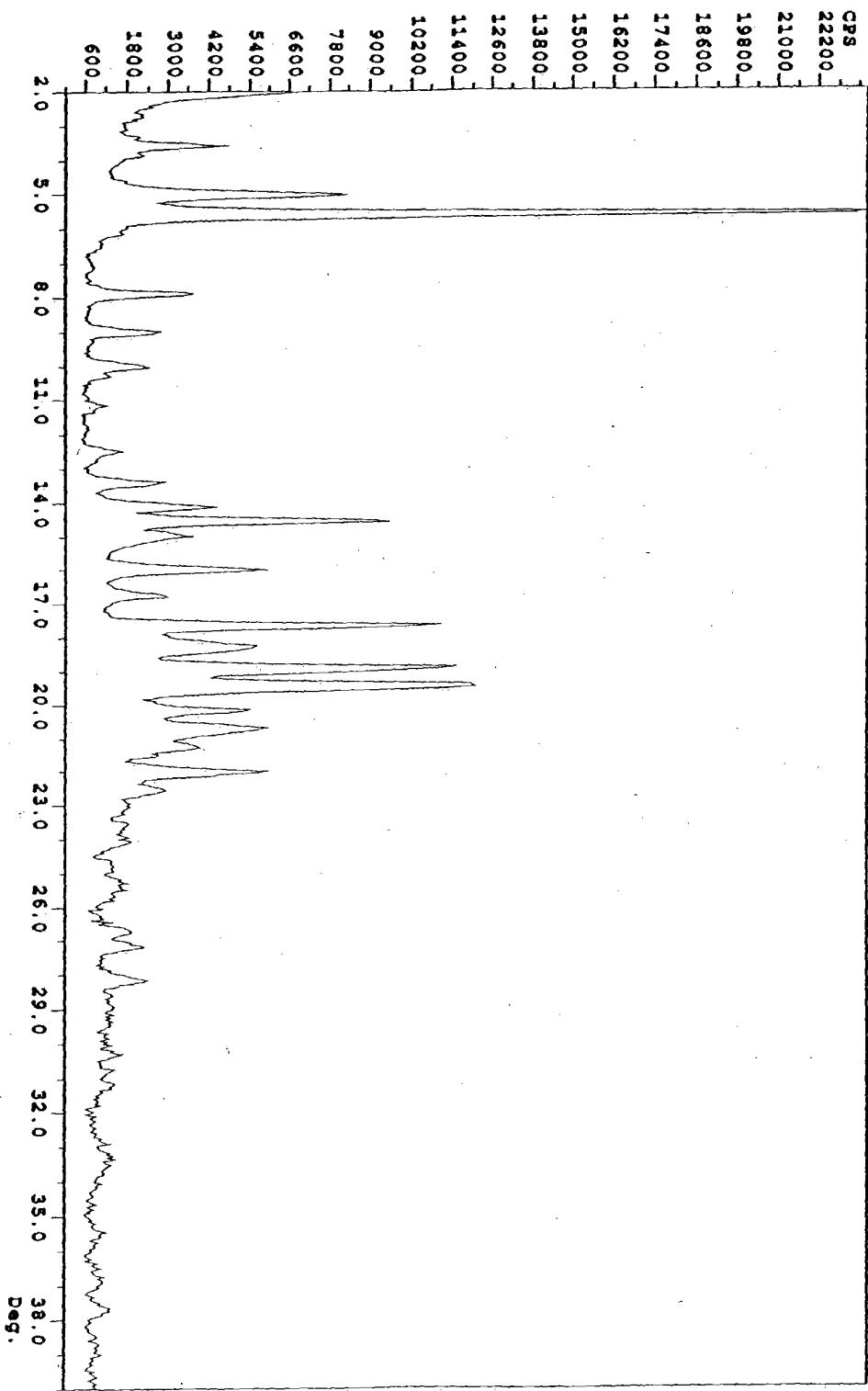


Fig 25

E

Step : 0.050° Cnt Time: 1.000 sec.
Range: 2.00 - 40.00 (Deg) Cont. Scan Rate : 3.00 Deg/min. TEVA

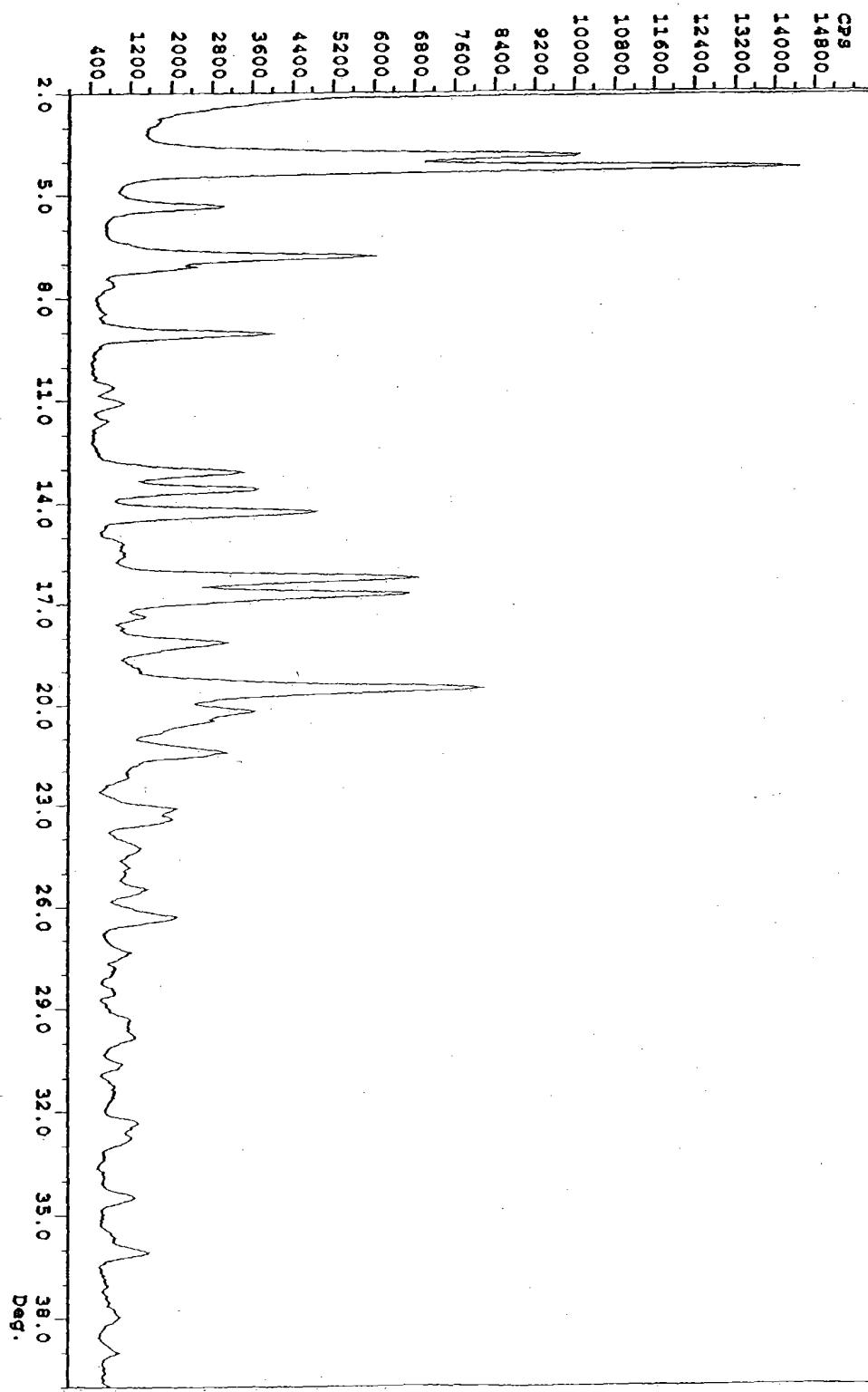


FIGURE 26

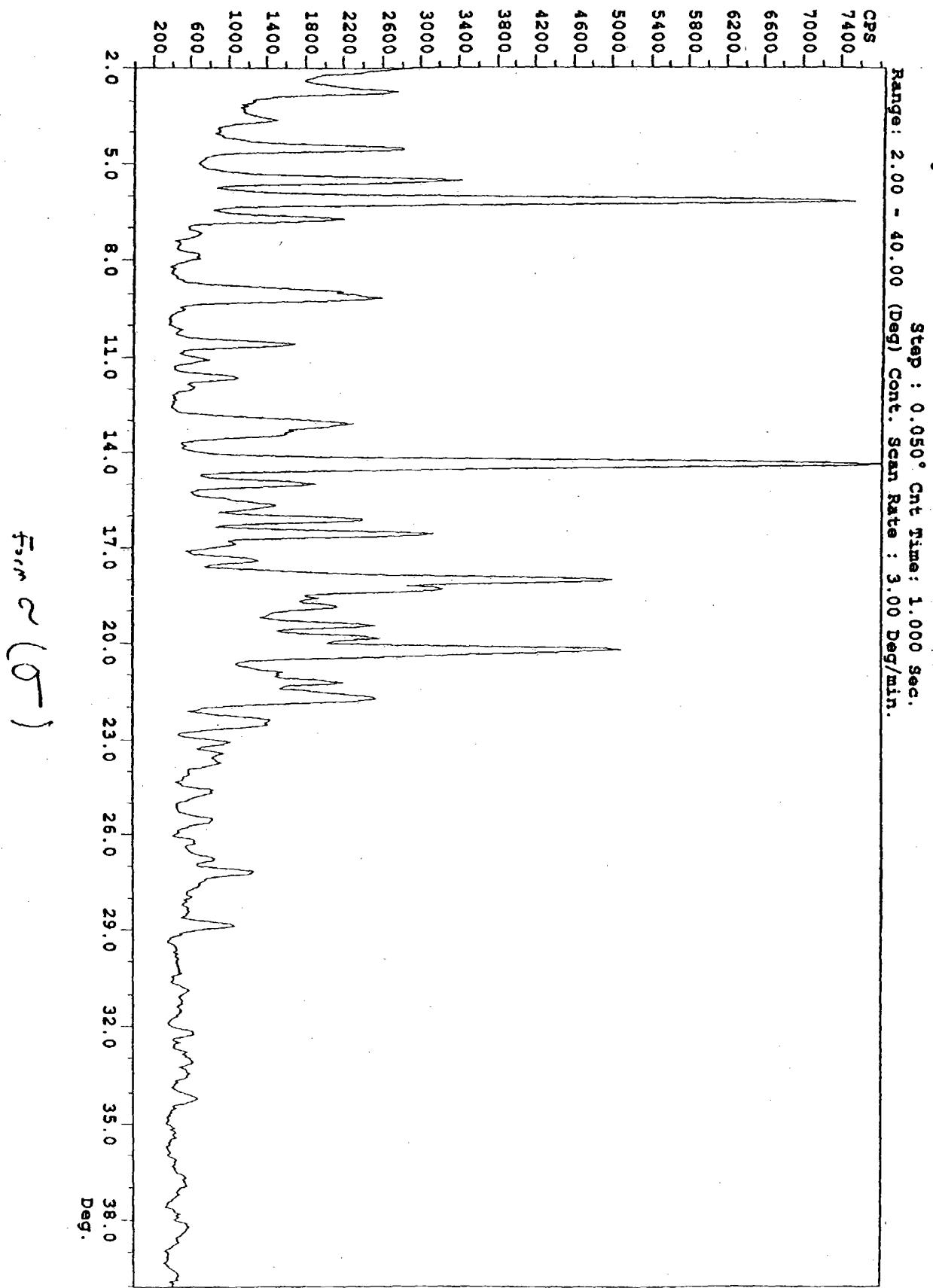
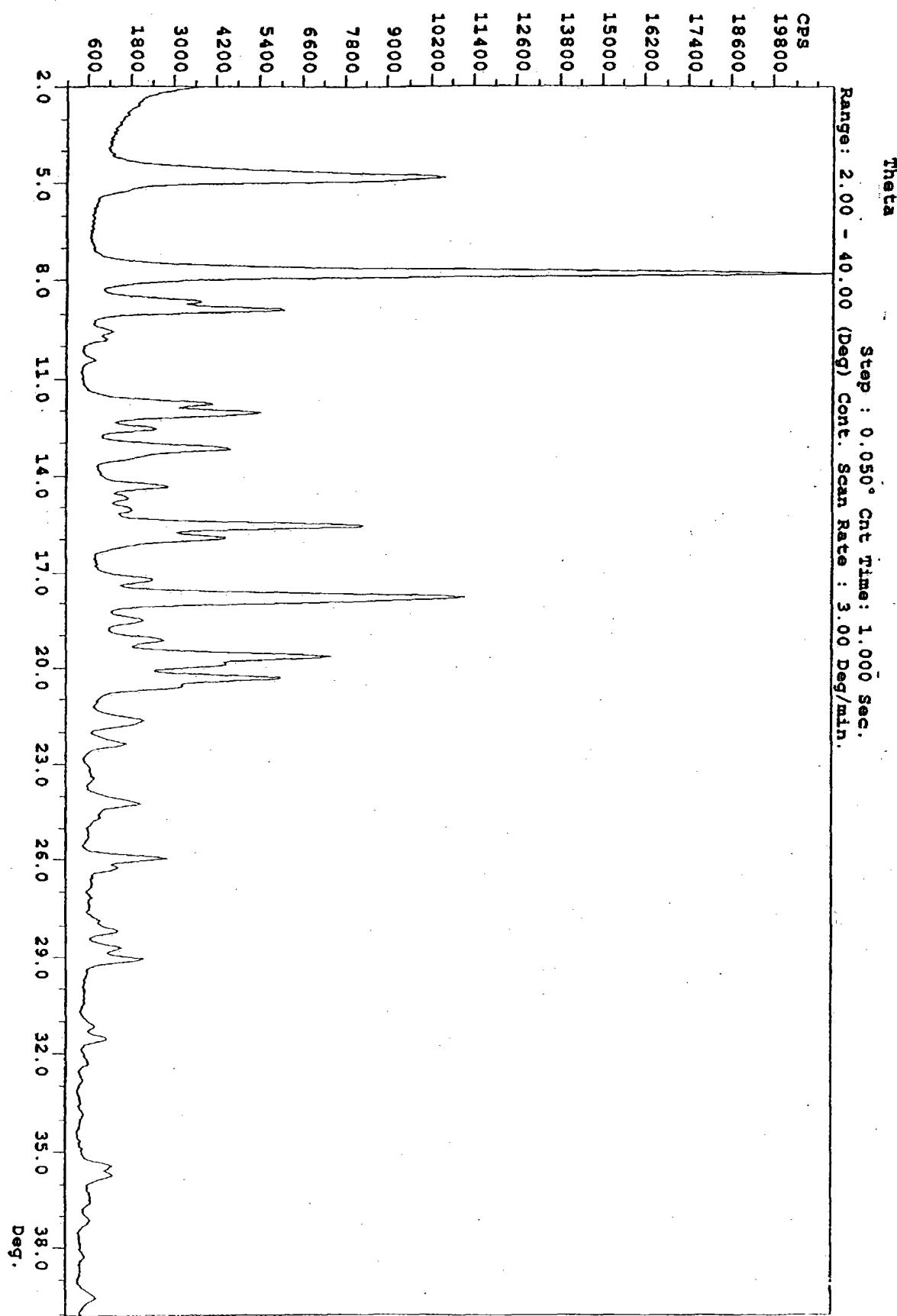


FIGURE 28



present velocity used to estimate net volumetric deposition by the different approaches
is shown in Table 1. The results are discussed below.

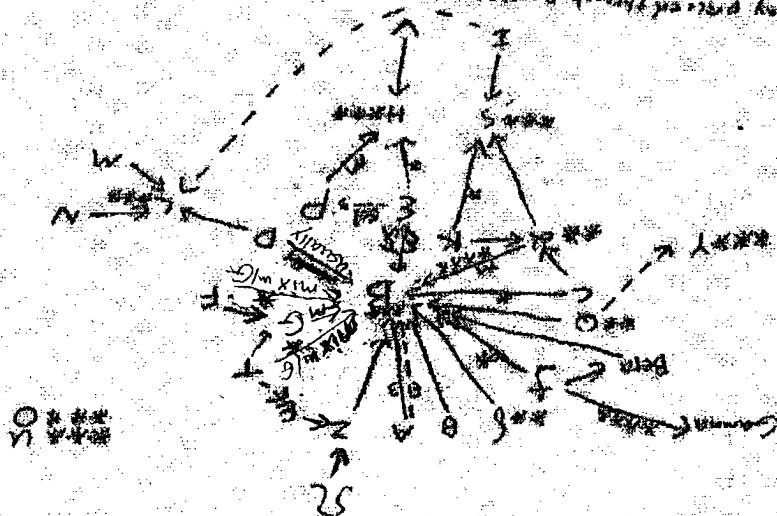
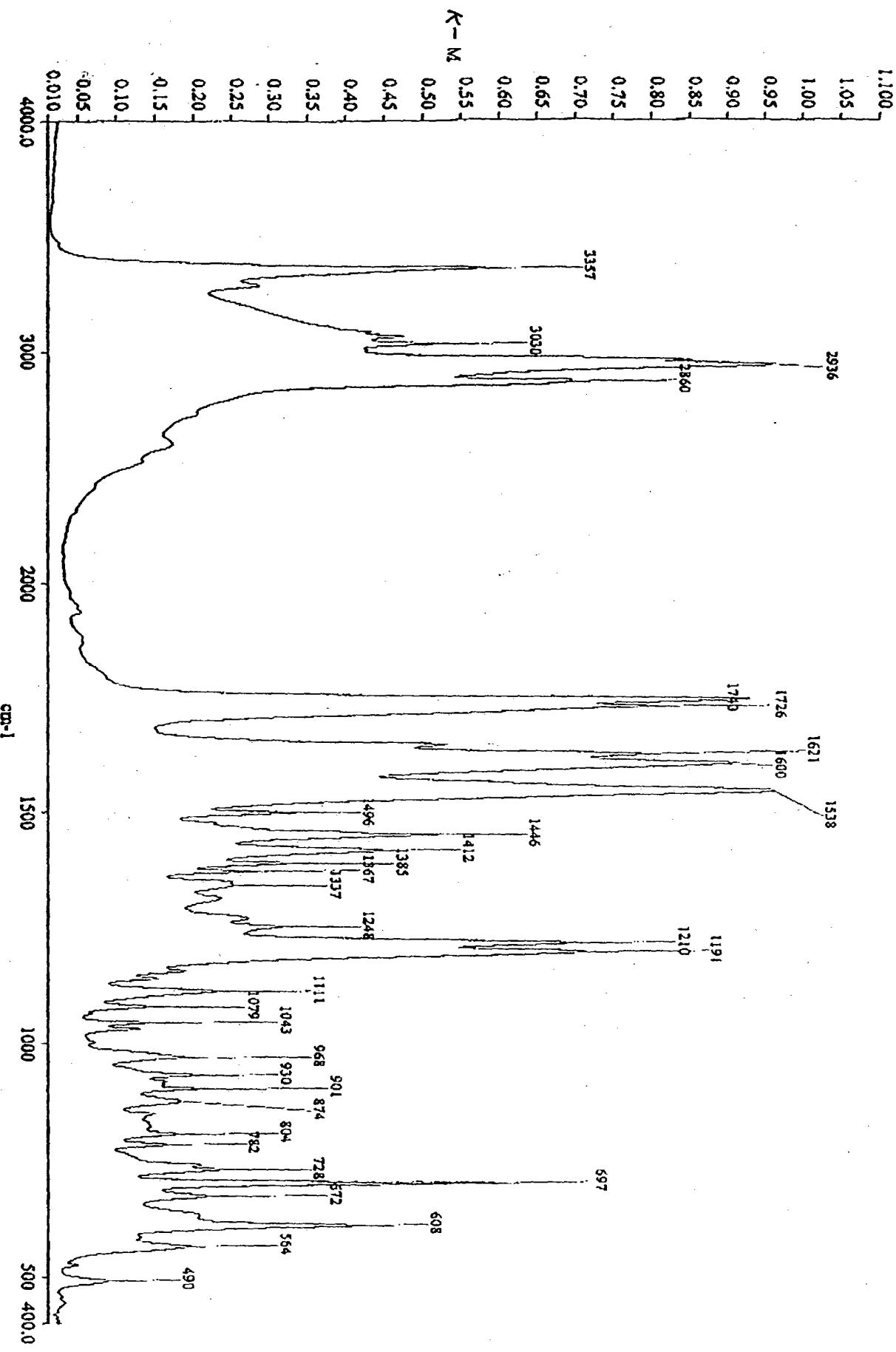


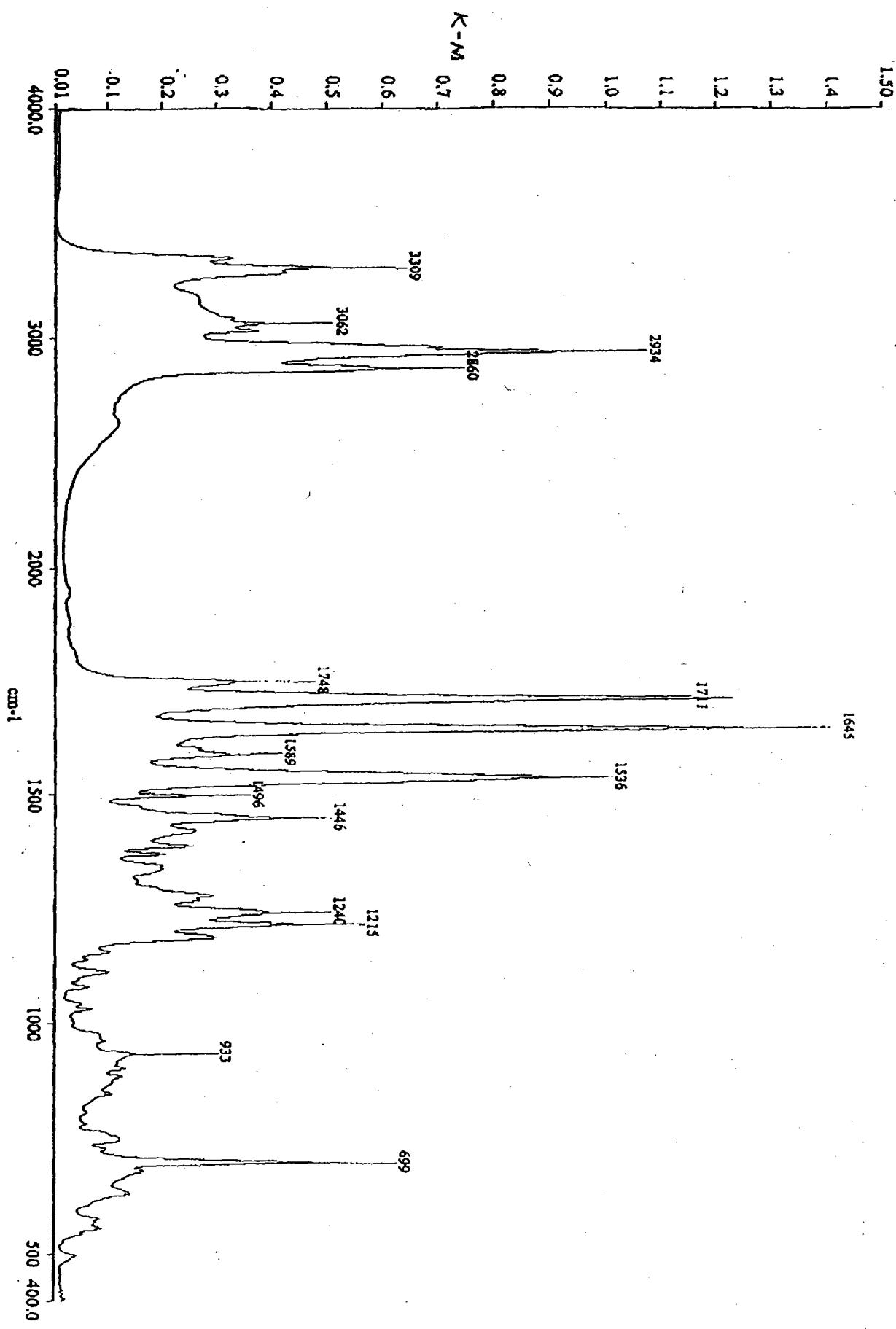
Figure 38 - Thermal stability chart

FIGURE 2
Form



- DRIFT, 4000-400 CM⁻¹, 16 scans, Resolution: 4.00cm⁻¹

FIGURE 30
Form P



DRIFT, 4000-400 CM⁻¹, 16 scans, Resolution: 4.00 cm⁻¹

FIGURE 5b
Form U

-DRIFT, 4000-400cm⁻¹, 16 scans, resolution: 4.0cm⁻¹

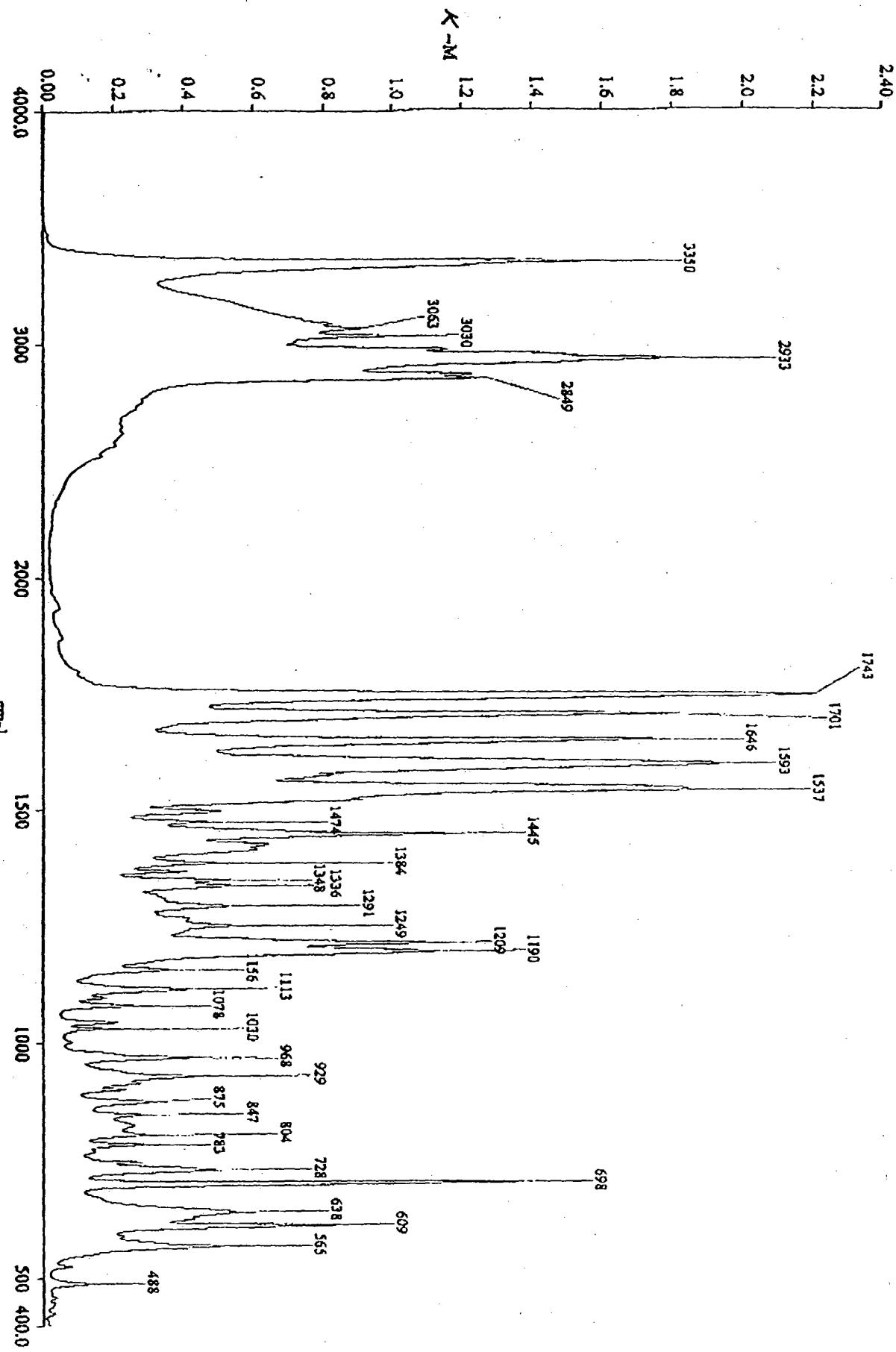


Figure 32 - Nateglinide Form Z

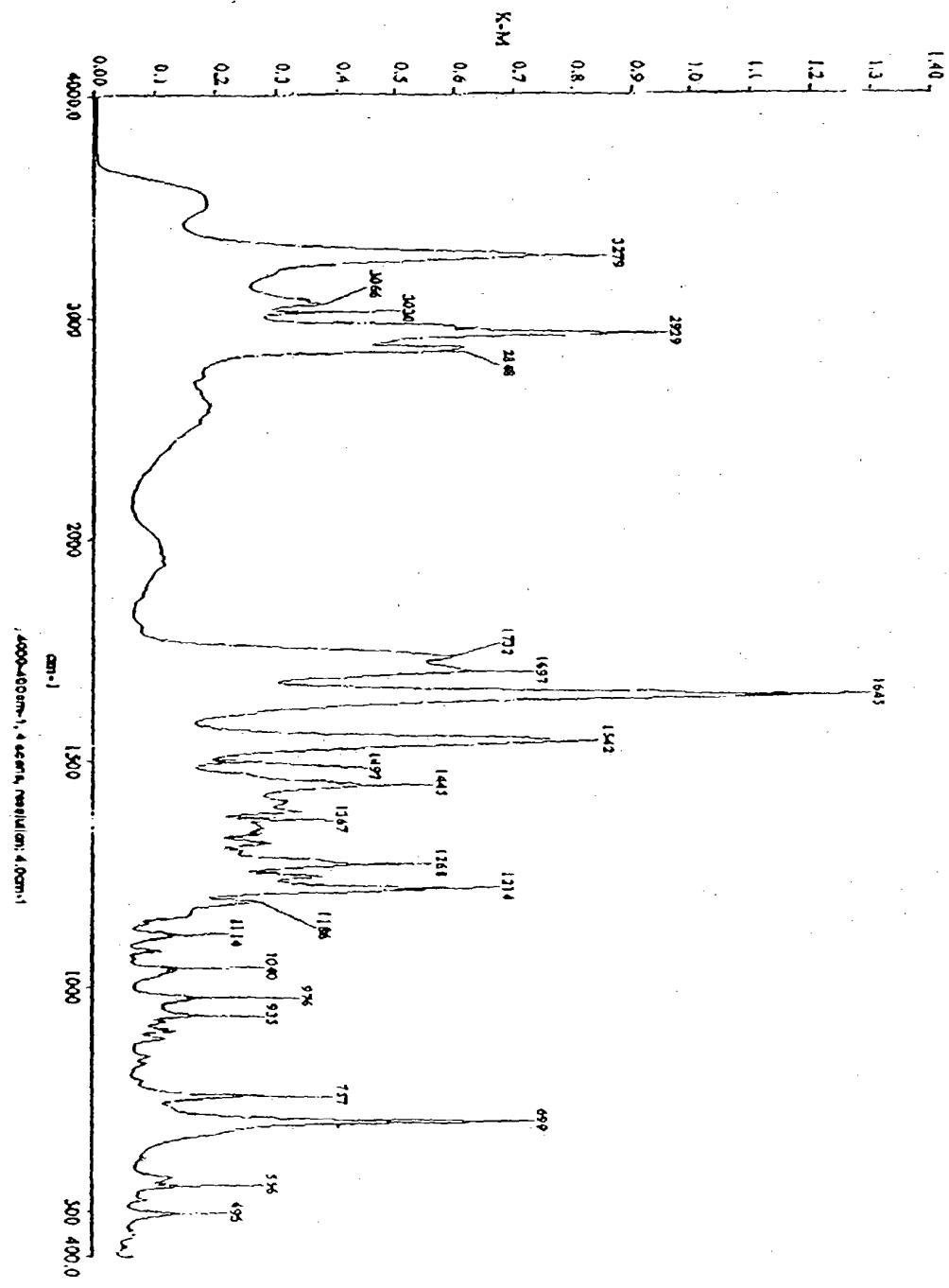
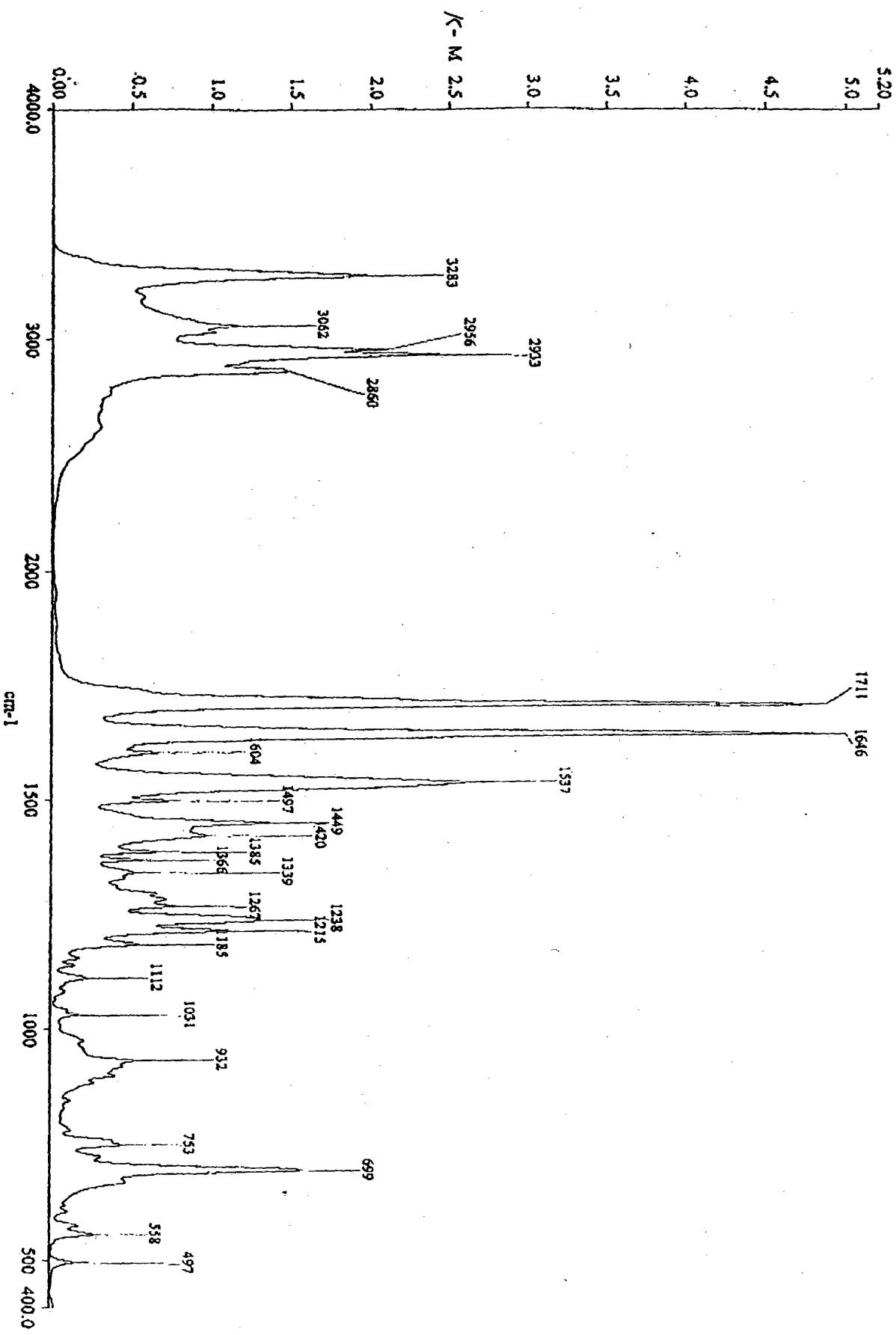


FIGURE 33
Run α



DRIFT, 4000-400 cm⁻¹, 16 scans, Resolution 4.00 cm⁻¹

FIGURE 34
Form delta

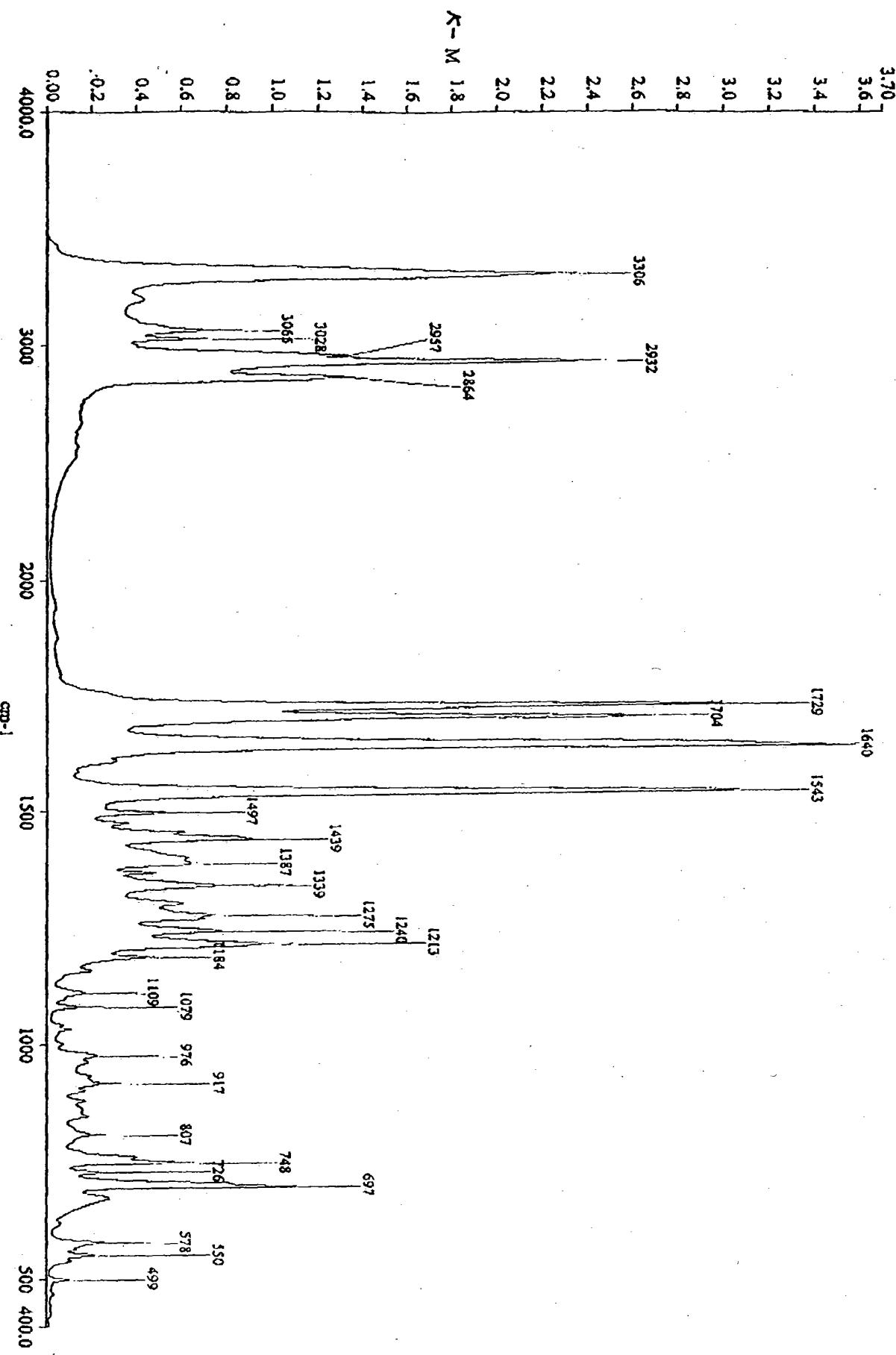


FIGURE 35 - Form O

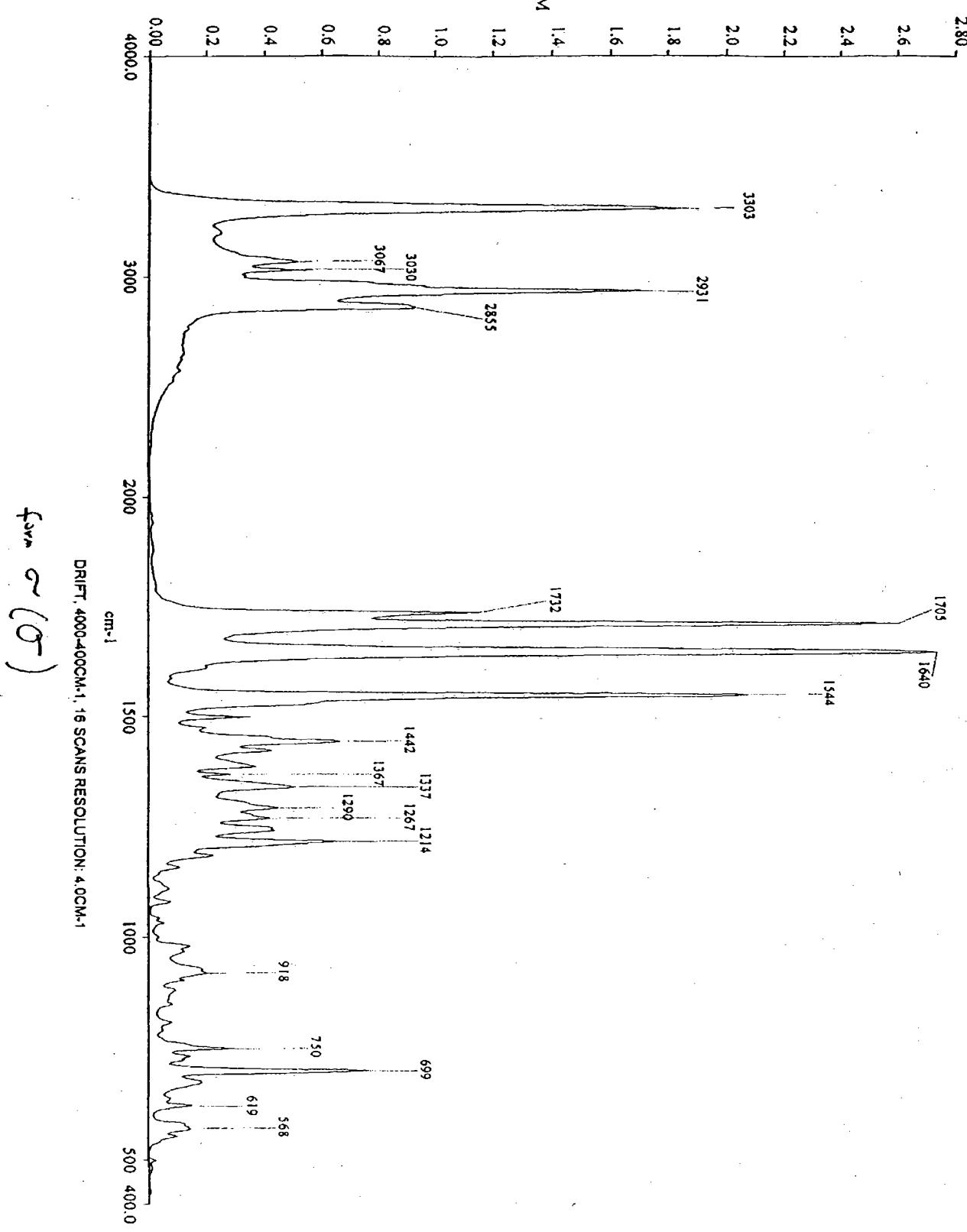
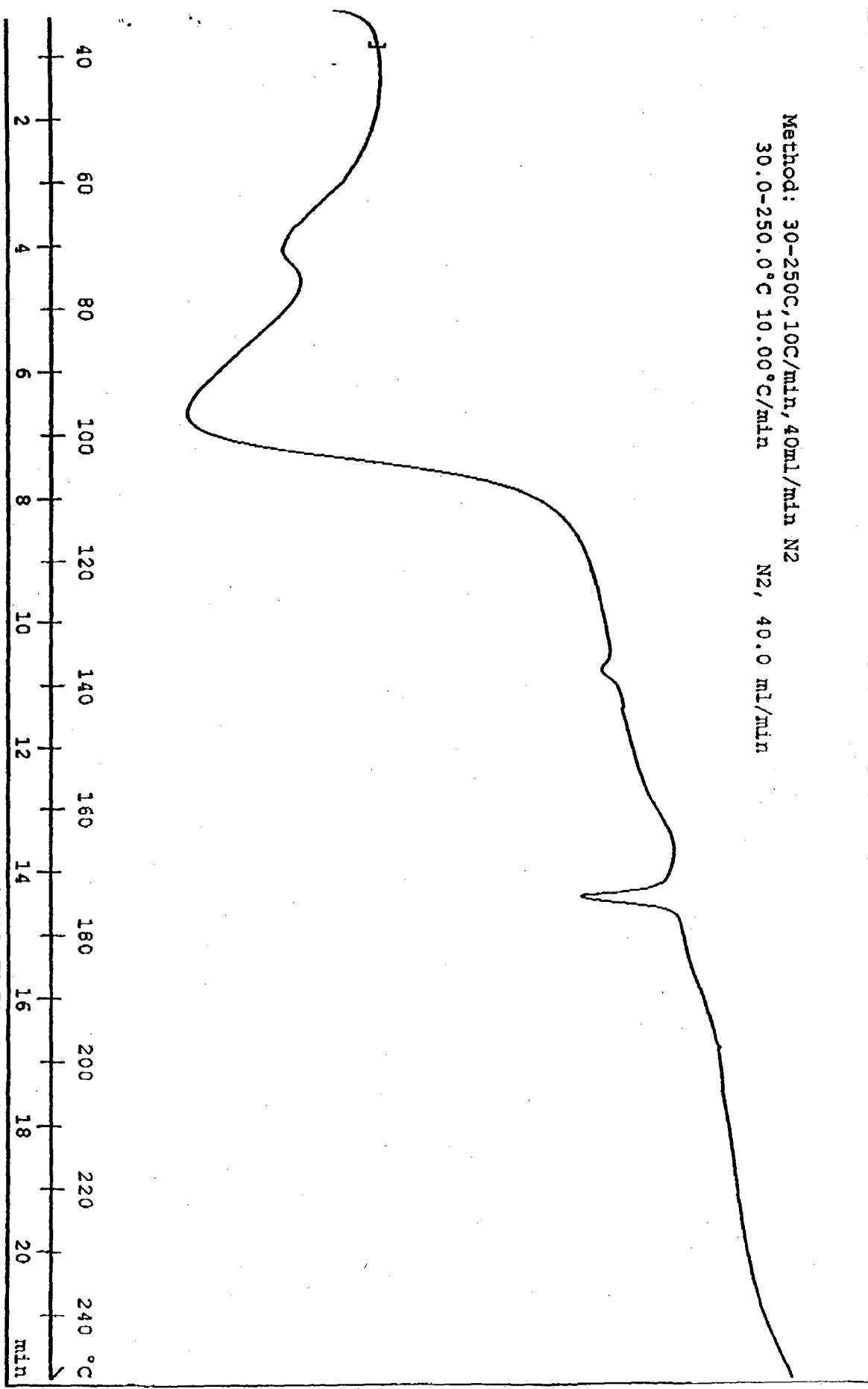


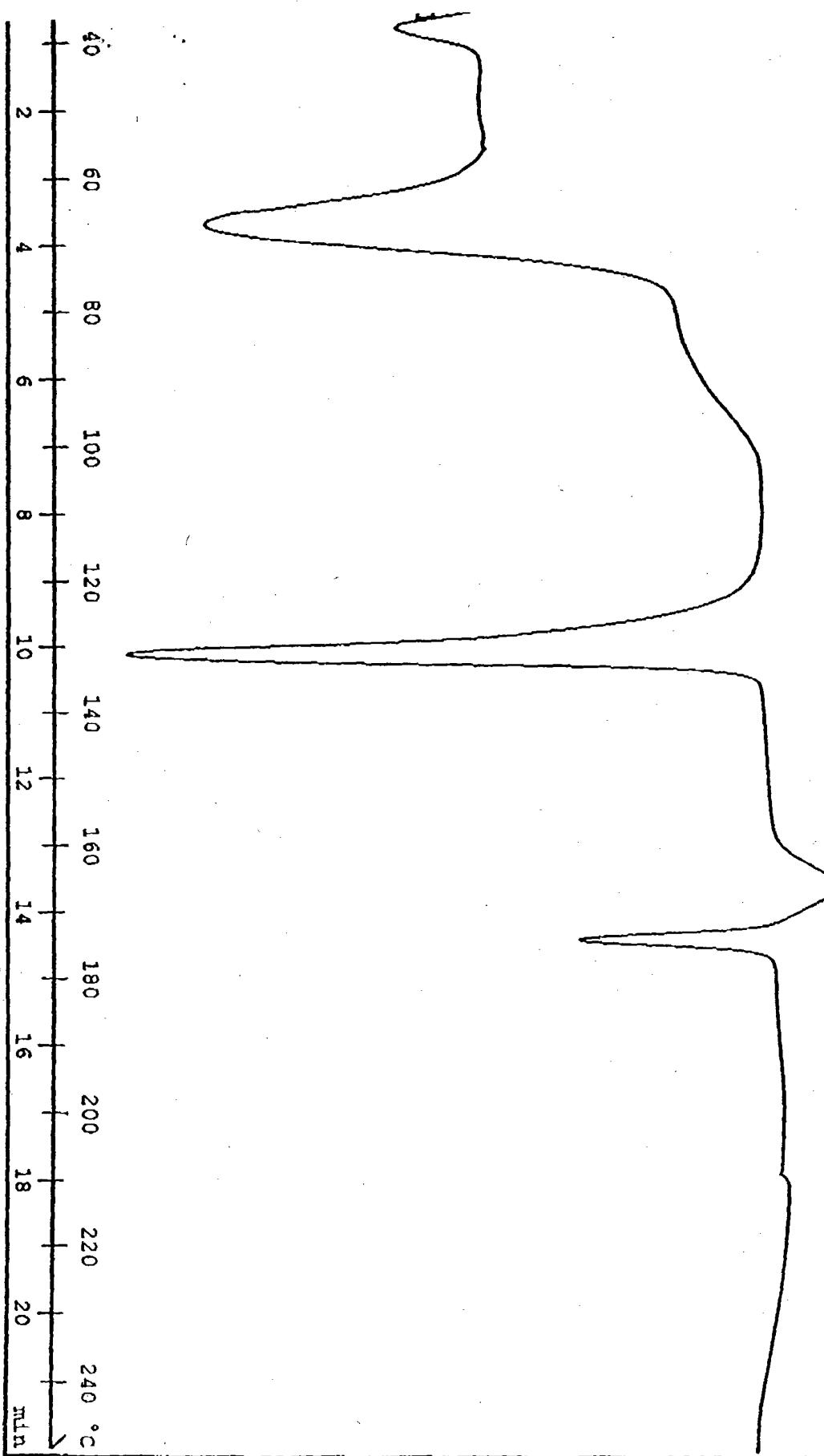
FIGURE 3
Form A



METTLER TOLEDO STAR® System

FIGURE 37 Form D

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min
N2, 40.0 mL/min

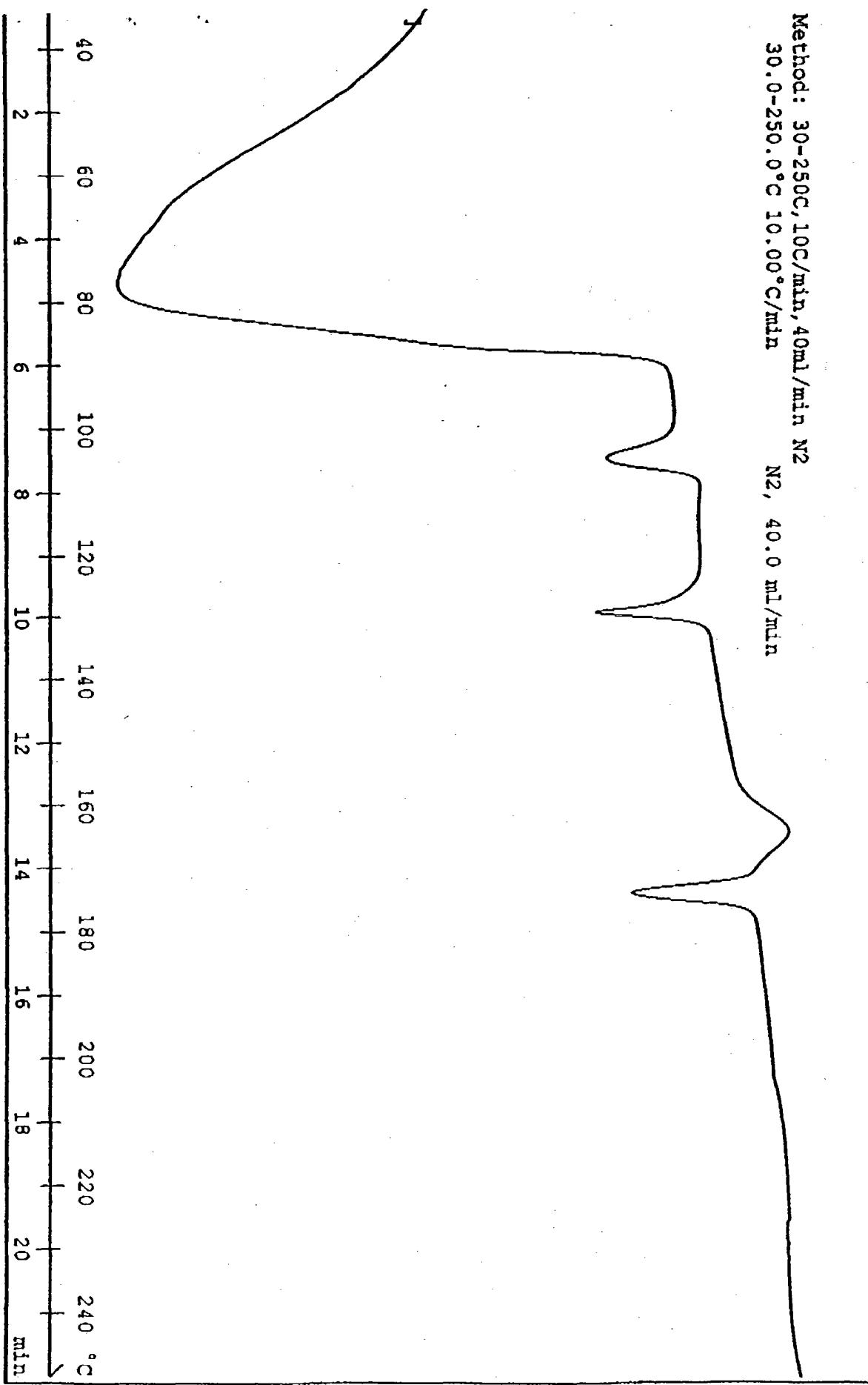


METTLER TOLEDO STAR® System

FIGURE 38

Form E

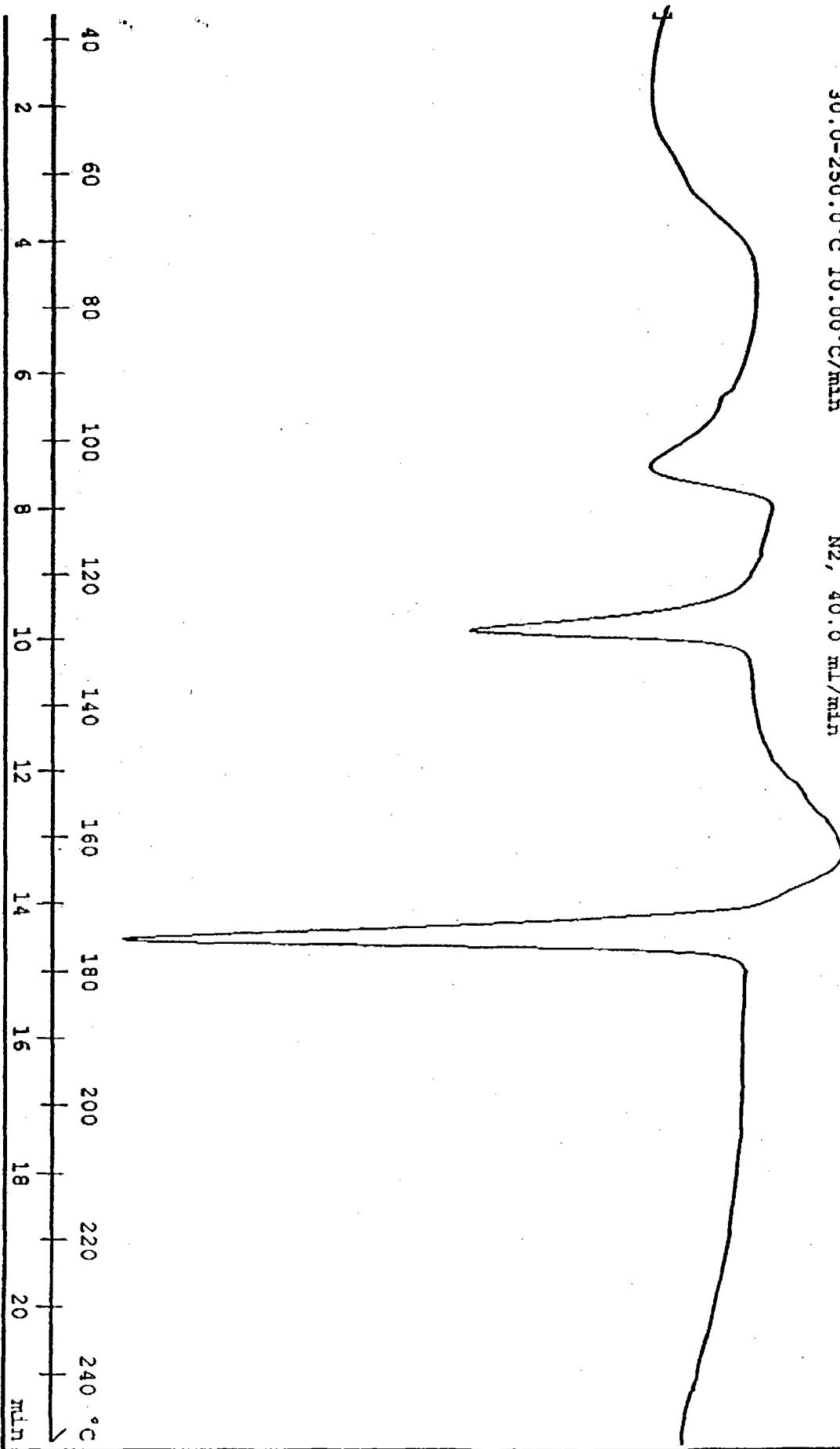
Method: 30-250C, 10C/min, 40ml/min N₂
30.0-250.0°C 10.00°C/min
N₂, 40.0 ml/min



METTLER TOLEDO STAR® System

39
FIGURE

Method: 30-250.0°C, 10C/min, 40mL/min N2
30.0-250.0°C 10.00°C/min
N2, 40.0 mL/min

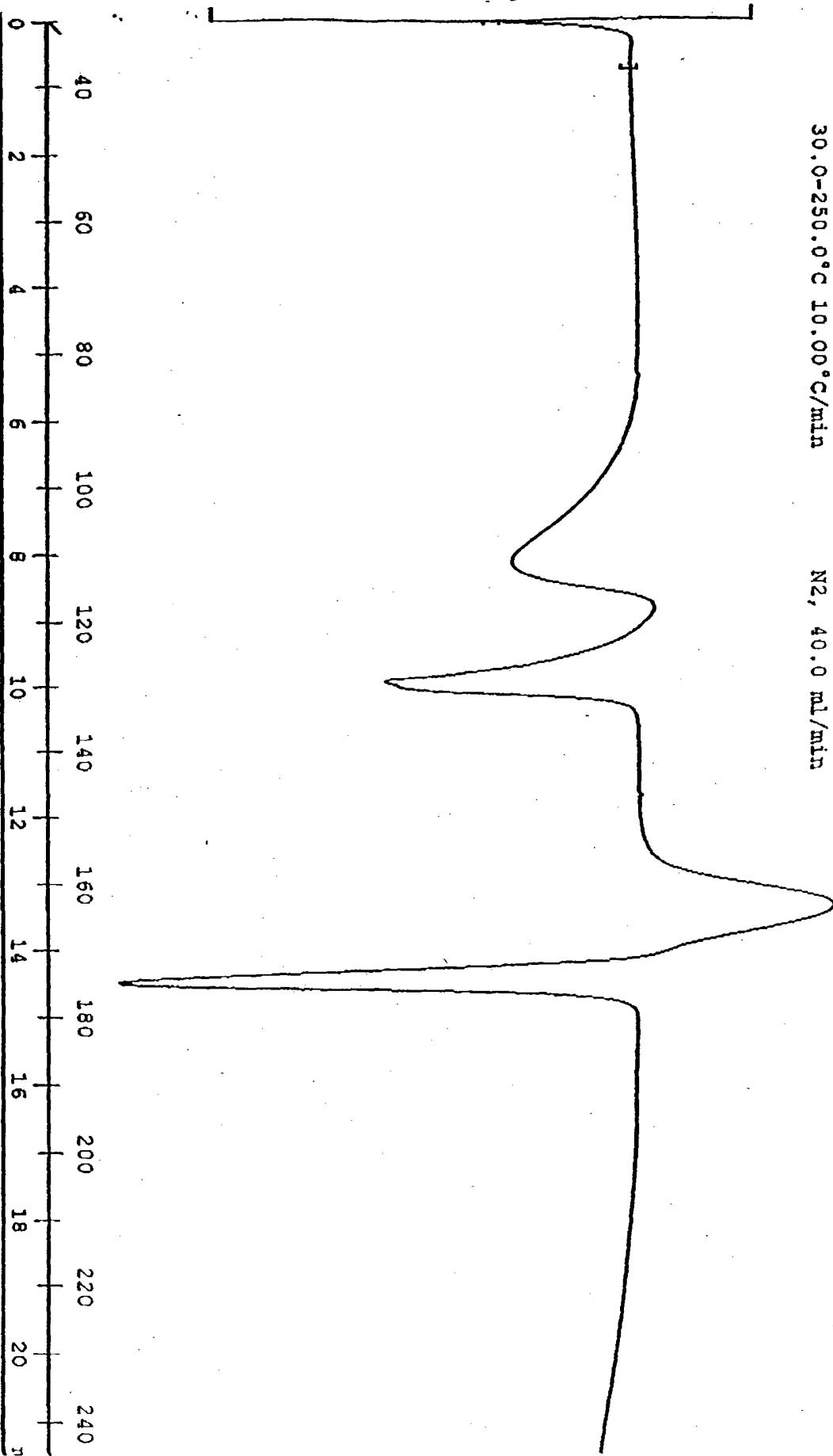


METTLER TOLEDO STAR® System

1XO

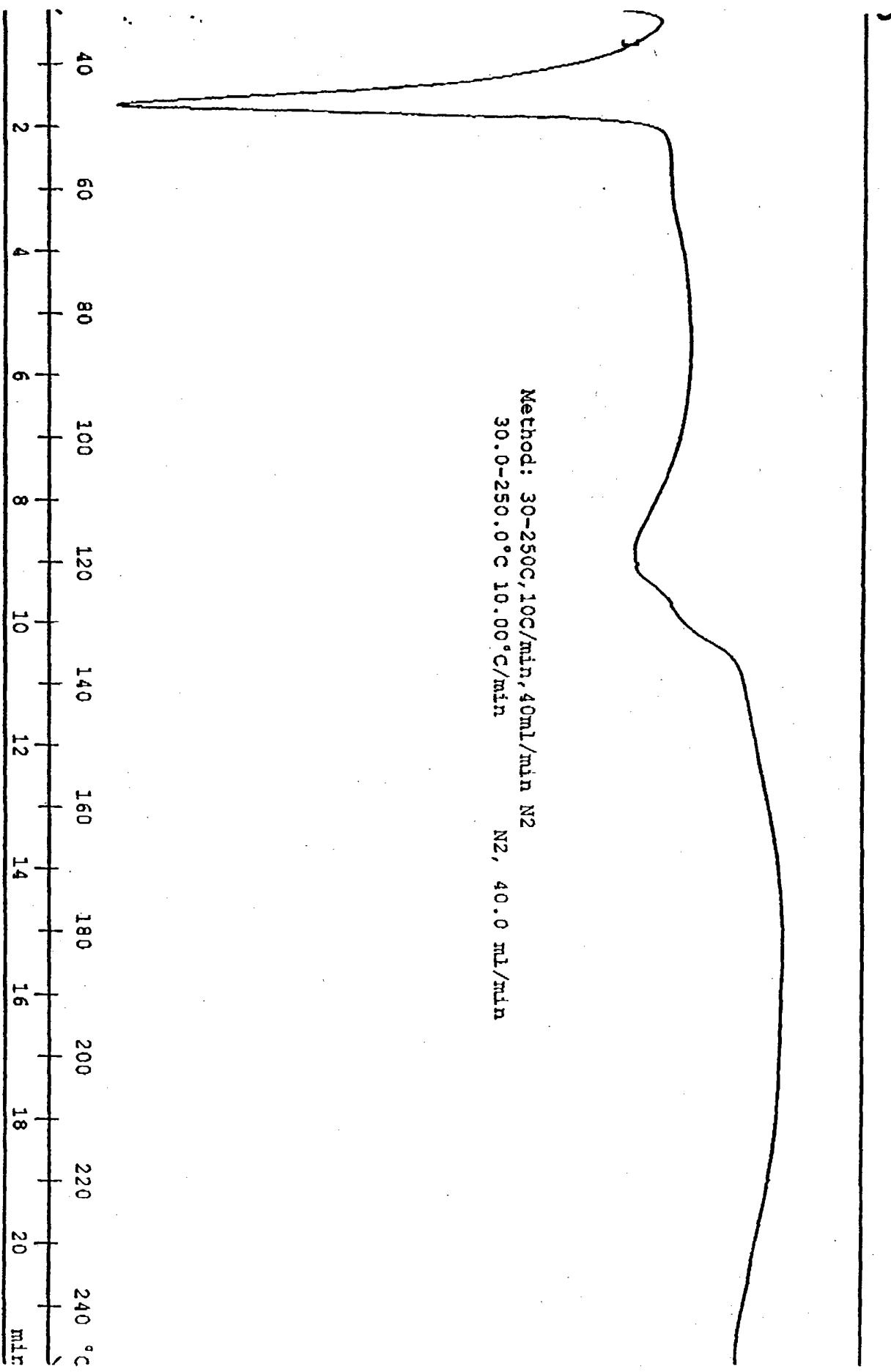
40
FIGURE 28

Method: 30-250C, 10C/min, 40ml/min N₂
30.0-250.0°C 10.00°C/min N₂, 40.0 ml/min



METTLER TOLEDO STAR System

FIGURE 41
Form I



METTLER TOLEDO STAR® System

FIGURE 49
Form T

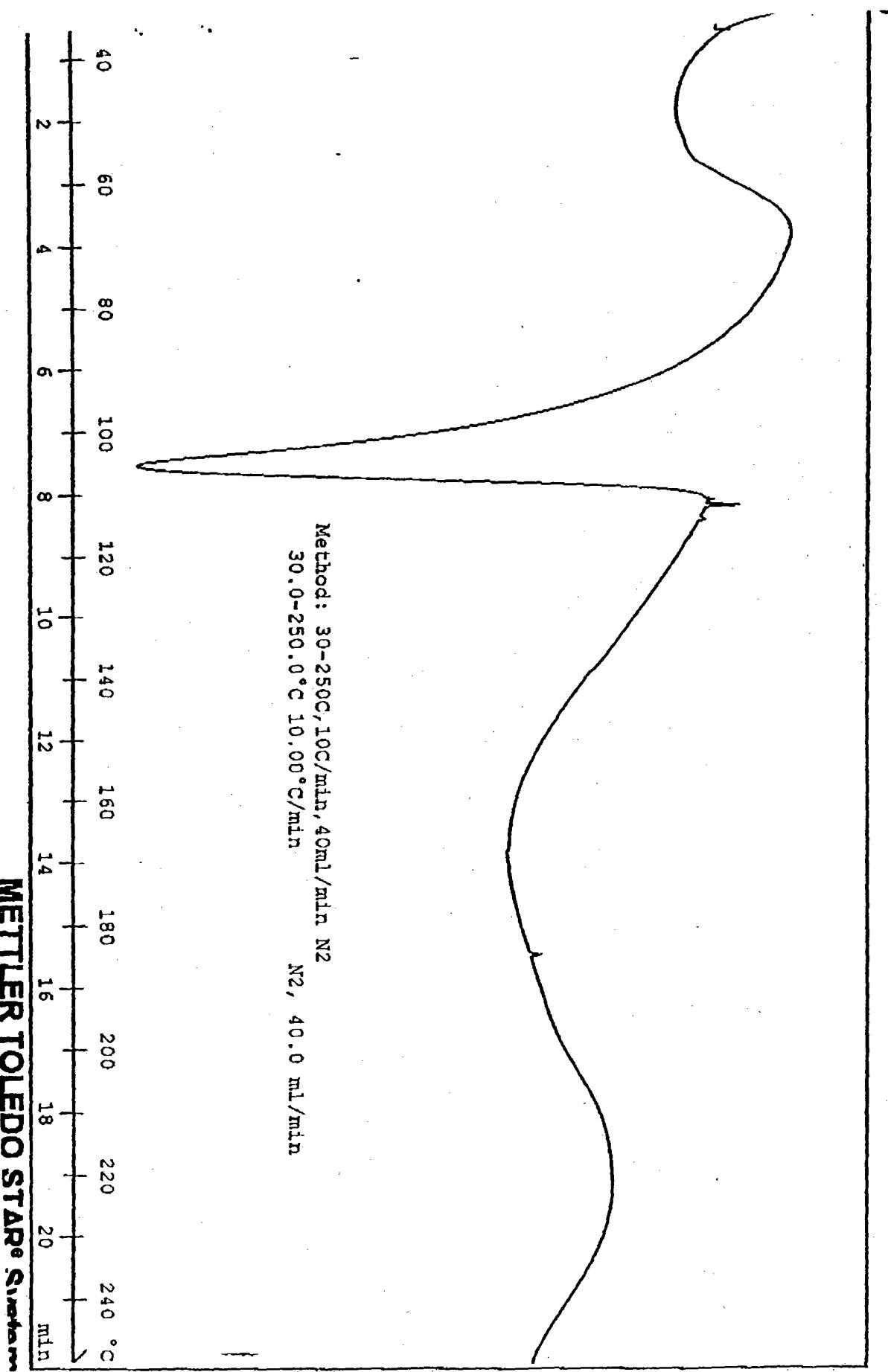


FIGURE 43
Form K

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min. N2, 40.0 ml/min

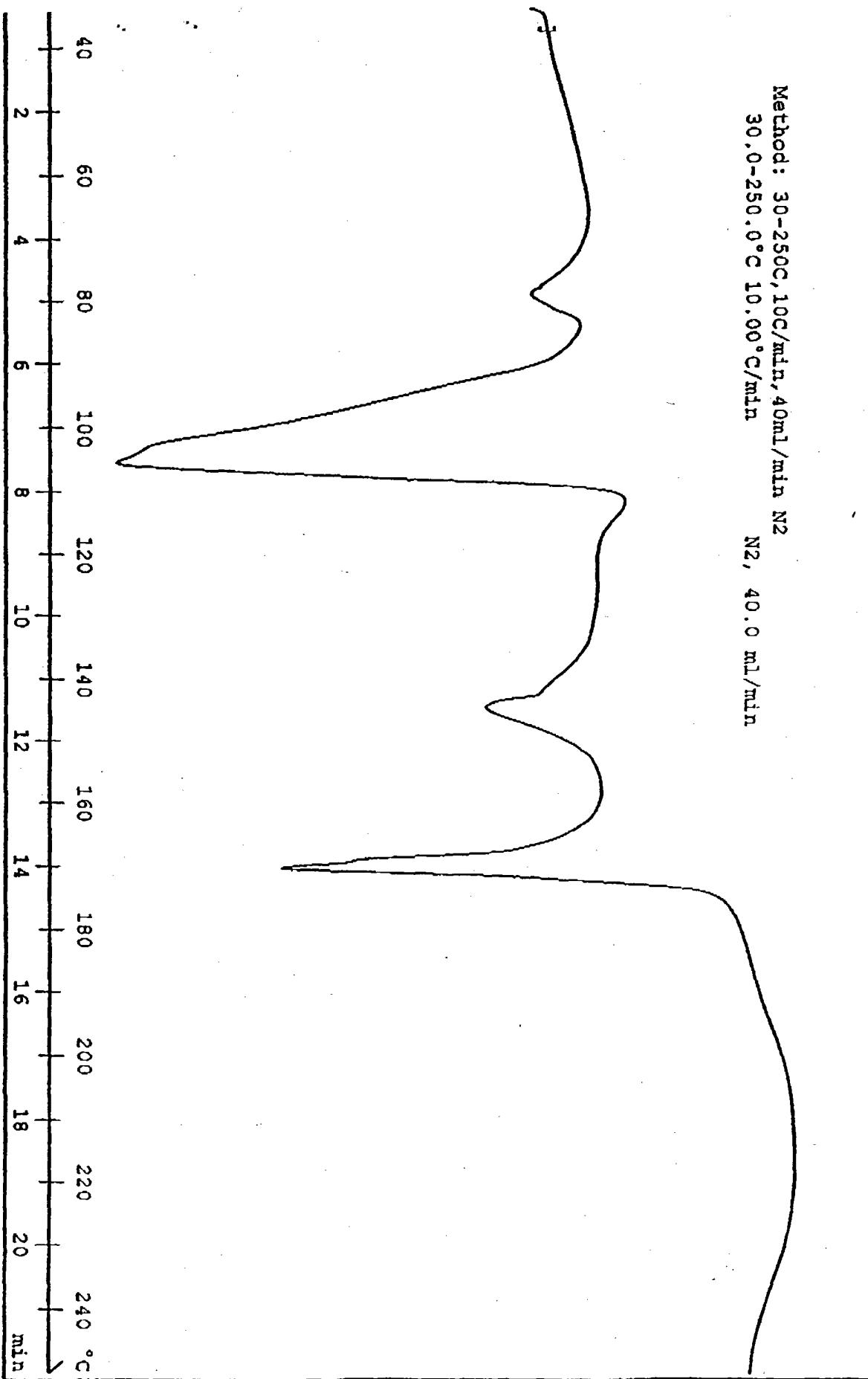
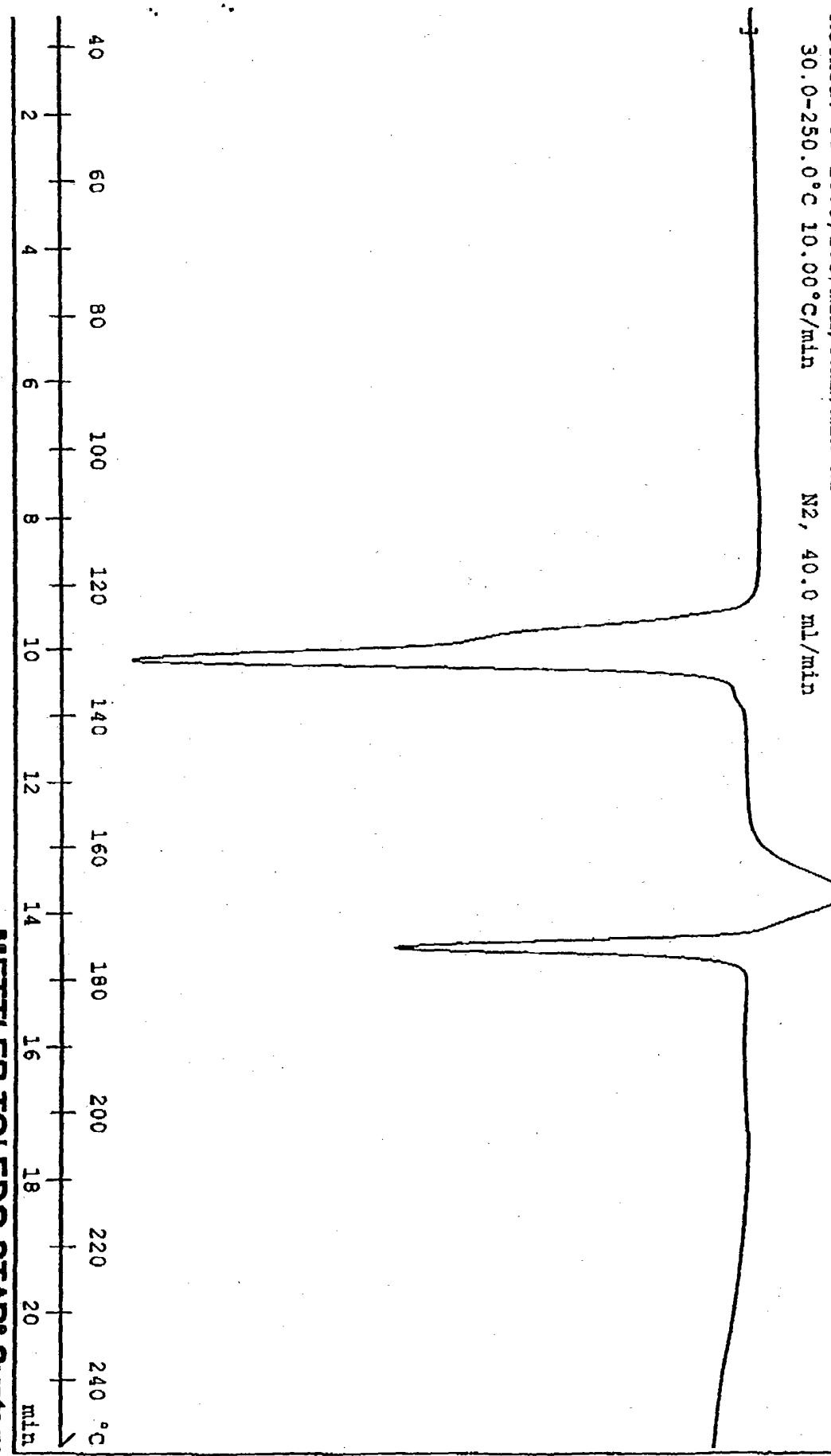


FIGURE 42 U14
Form L

Method: 30-250°C, 10C/min; 40ml/min N₂
30.0-250.0°C 10.00°C/min
N₂, 40.0 mL/min



METTLER TOI FN STAB 0.1 mg

Figure 45
Form M

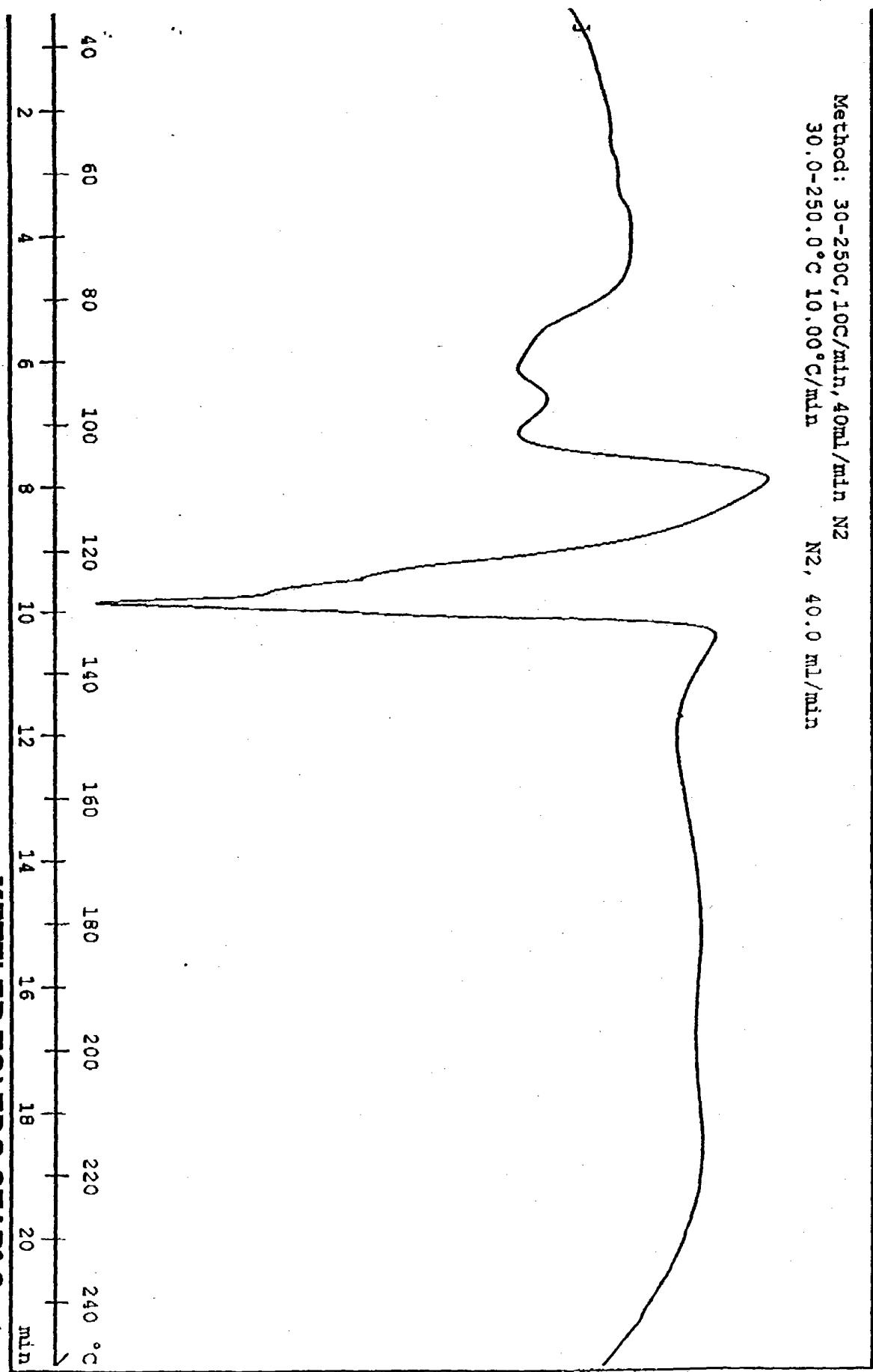


FIGURE 46
Form N

Method: 30-250°C, 10C/min, 40mL/min N₂
30.0-250.0°C 10.00°C/min N₂, 40.0 mL/min

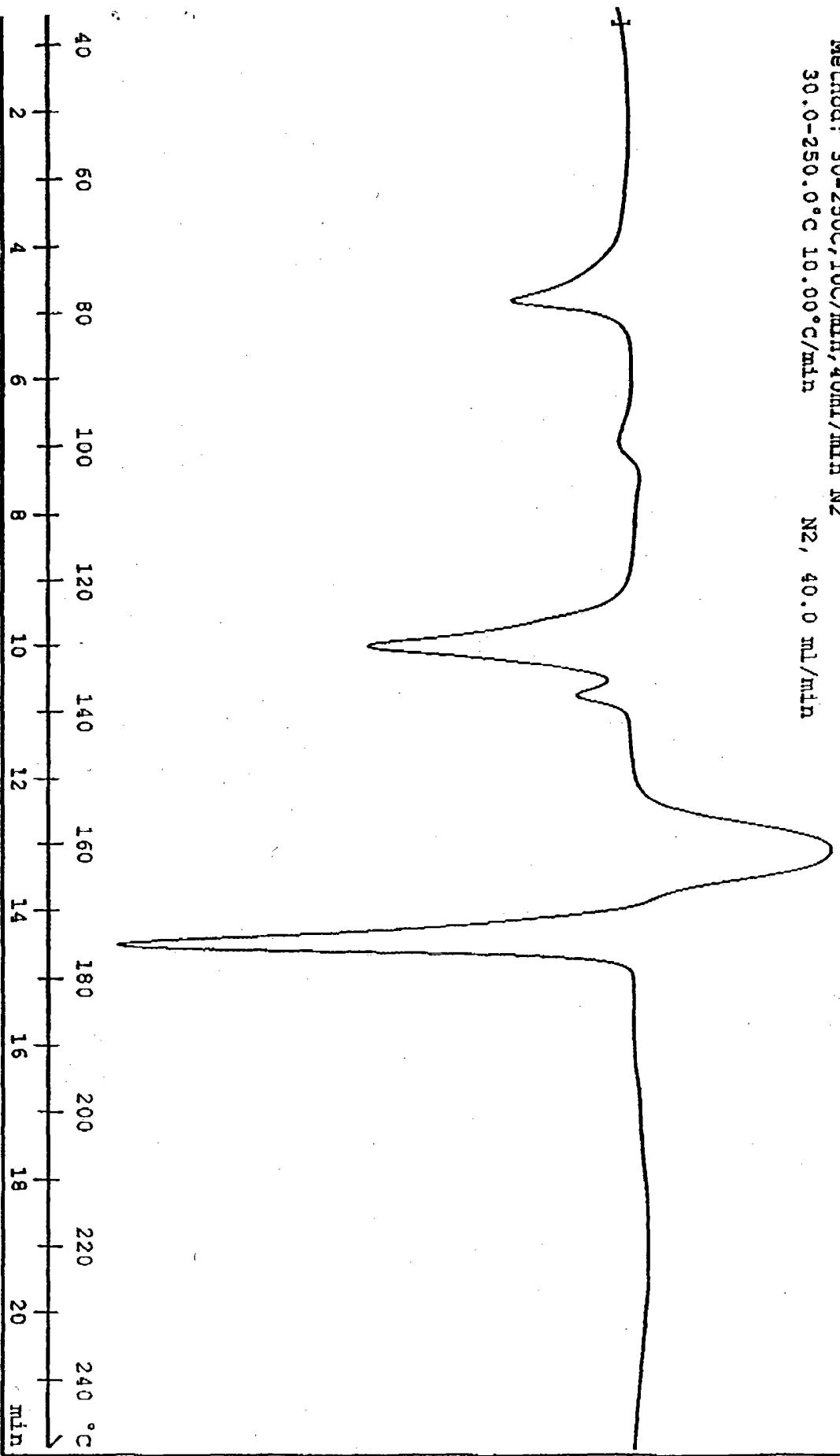
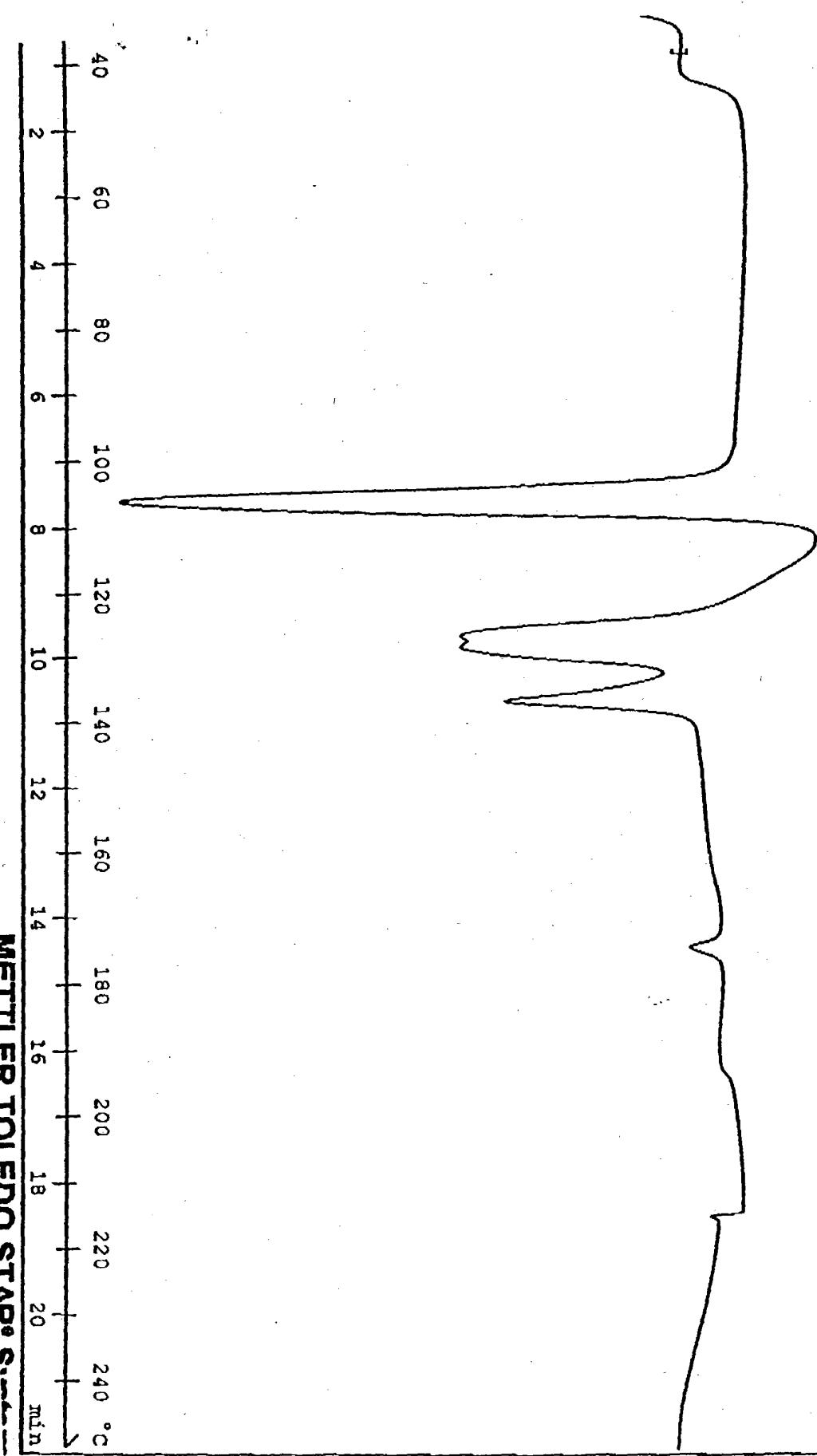


FIGURE 45 U7
Form C

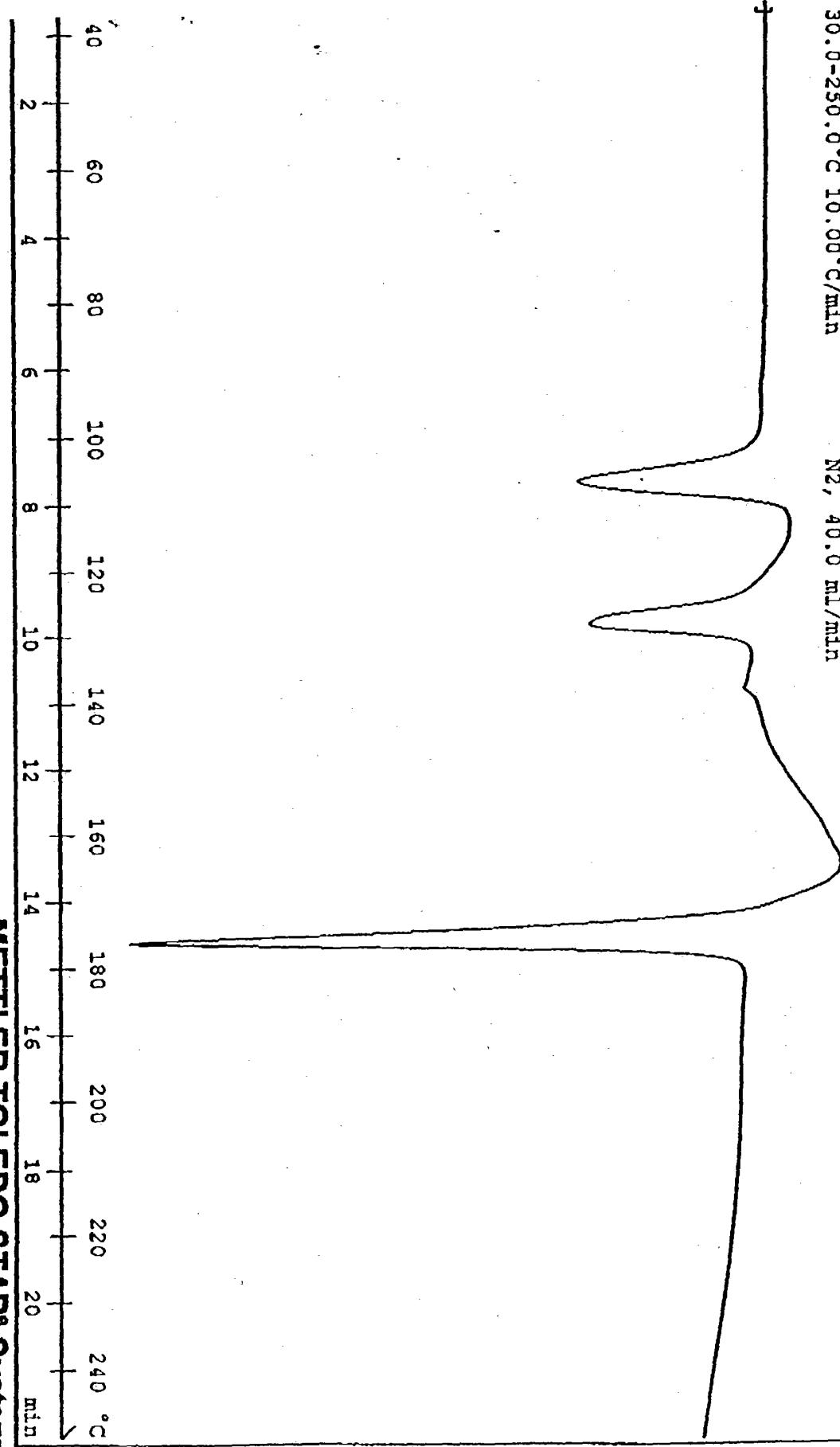
Method: 30-250C, 10C/min, 40ml/min N₂
30.0-250.0°C 10.00°C/min
N₂, 40.0 ml/min



METTLER TOLEDO STAB® G

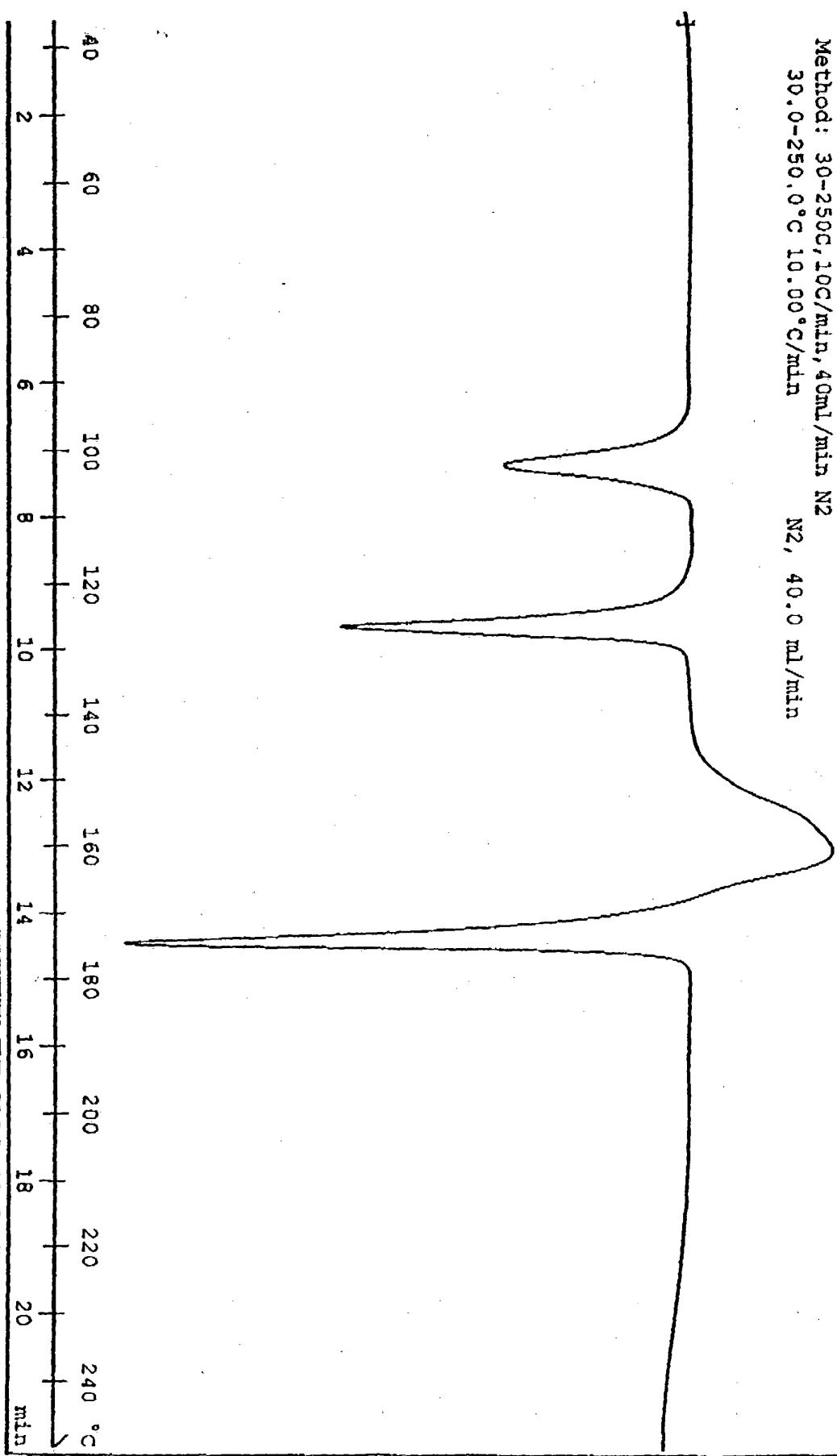
FIGURE 48
Form F

Method: 30-250C, 10C/min, 40mL/min N2
30.0-250.0°C 10.00°C/min N2, 40.0 mL/min



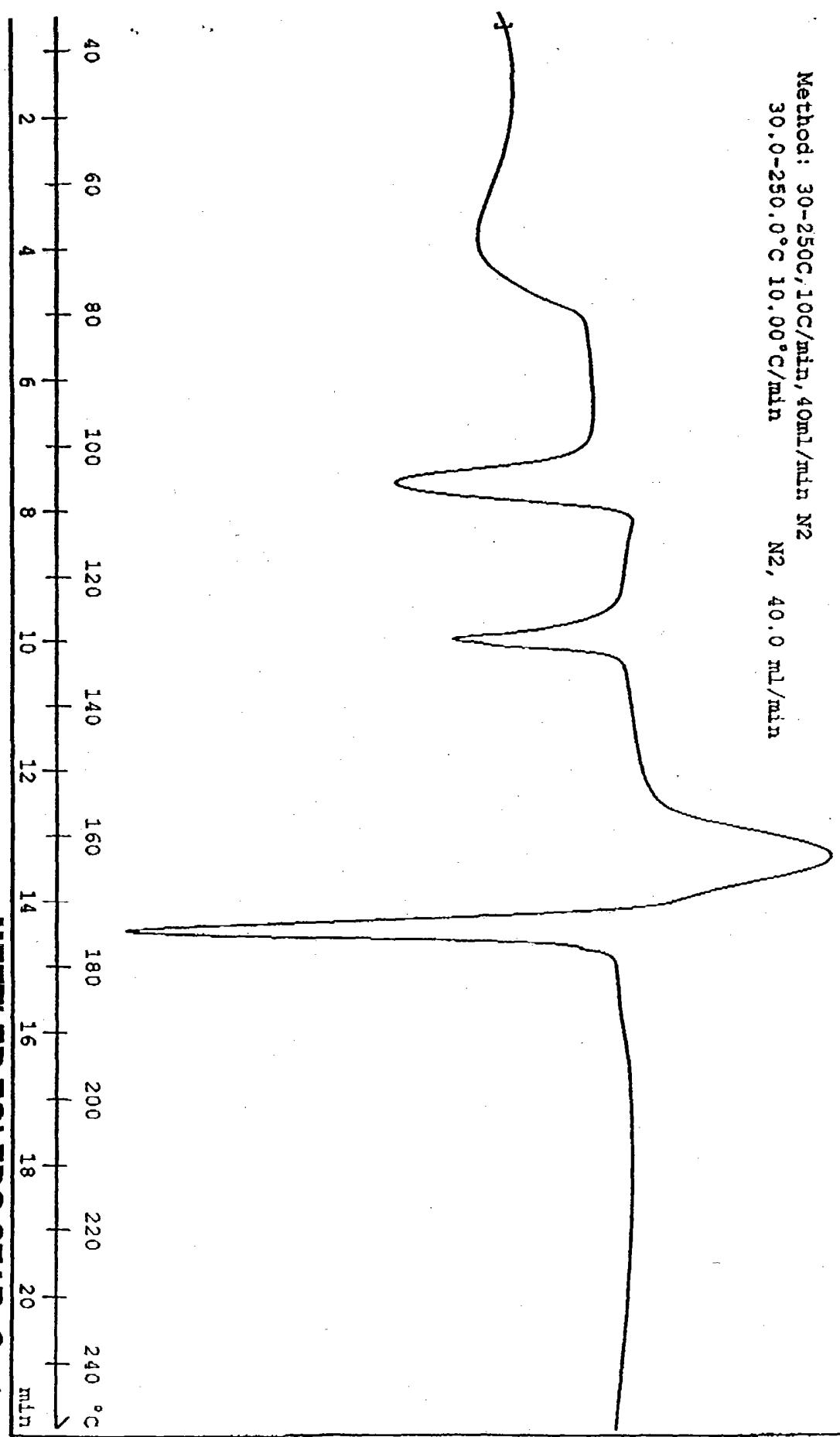
METTLER TOLEDO STAR® System

FIGURE 47 49
Form C



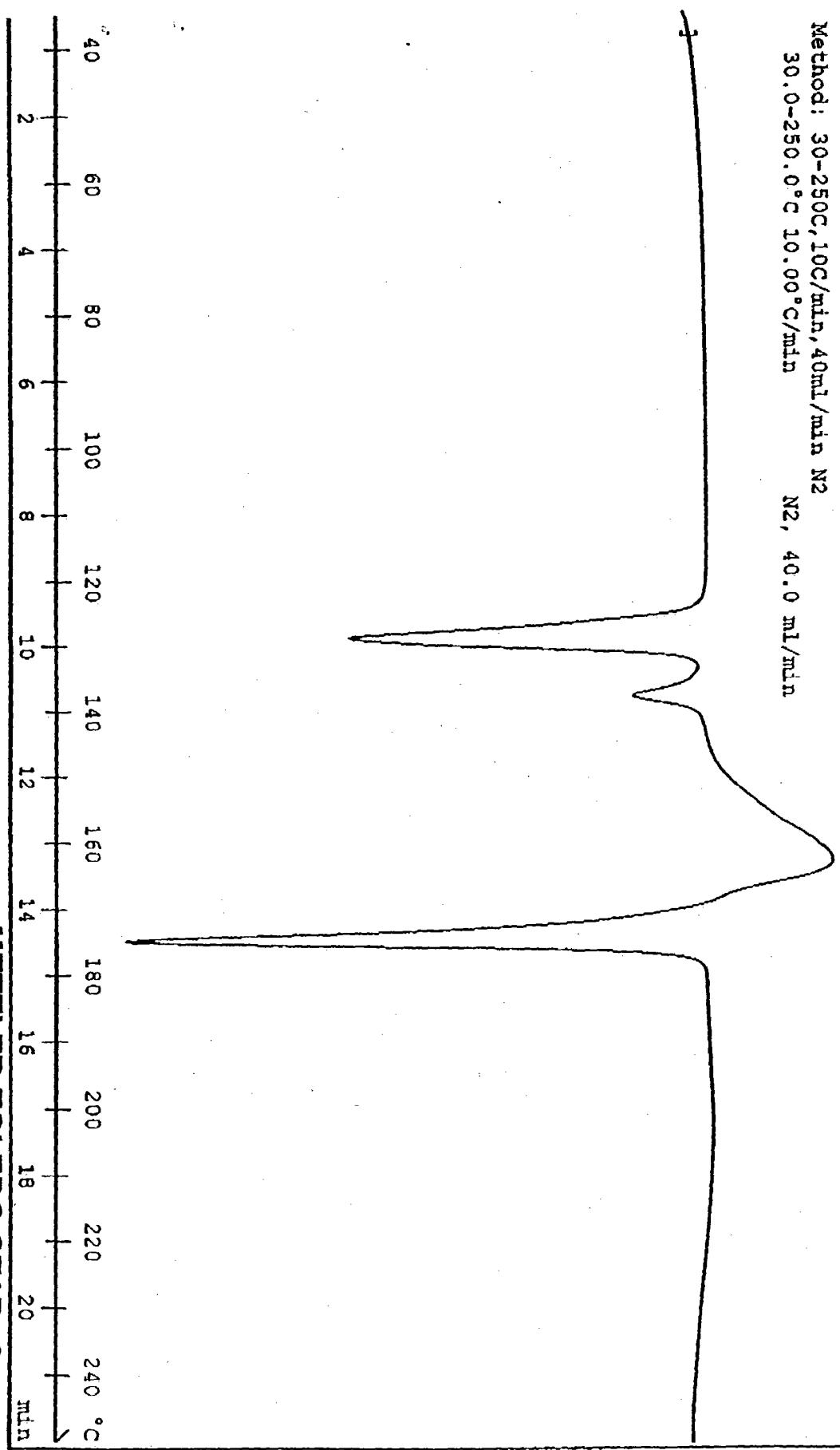
METTLER TOLEDO STAR® System

FIGURE 48 50
Form T



METTLER TOLEDO STAR System

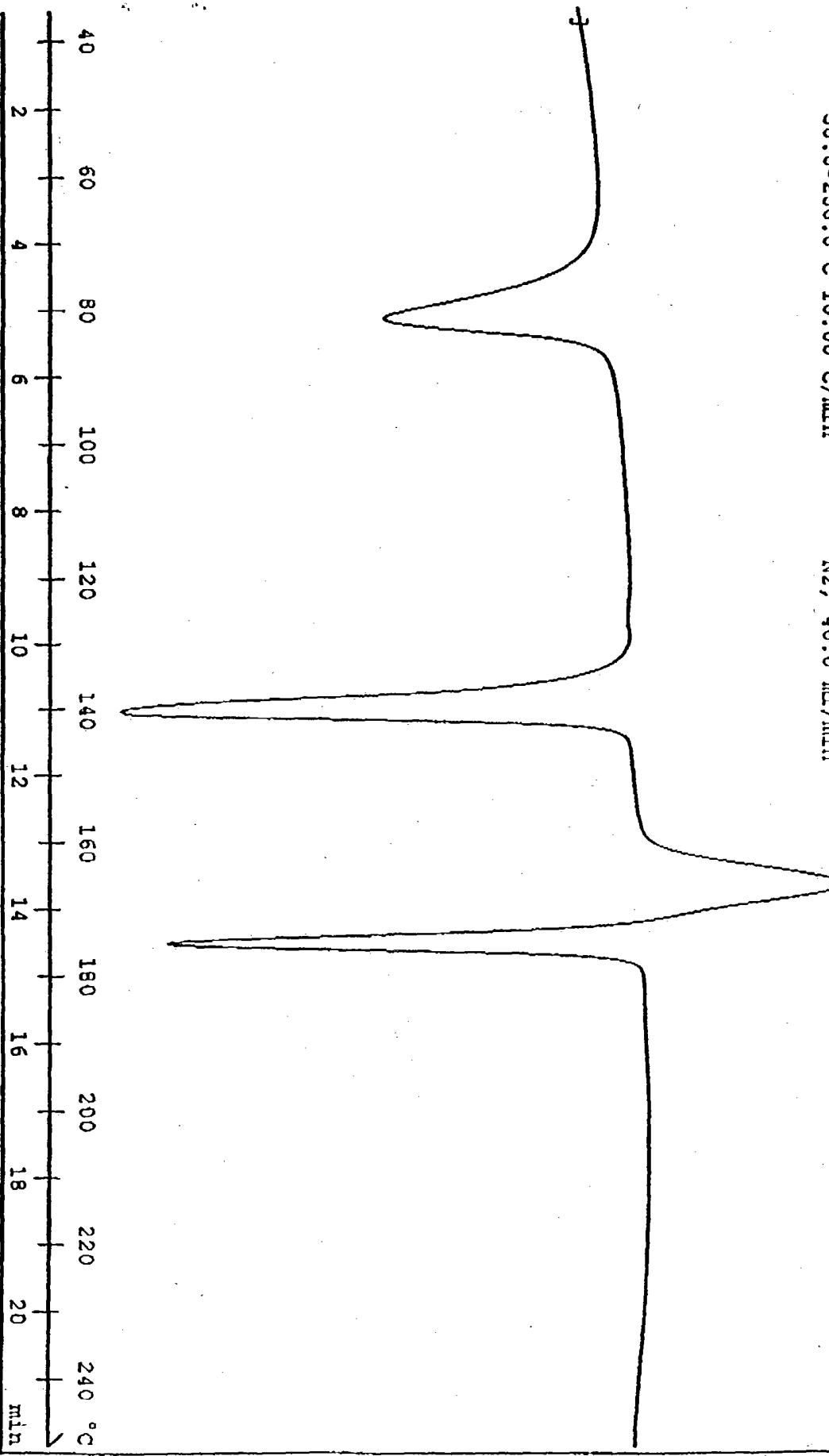
FIGURE 49. 51
Form W



METTLER TOLEDO STAR System

FIGURE 5-5 2
Form ✓

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min
N2, 40.0 ml/min



METTLER TOLEDO STAR System

FIGURE 52-53
Form Y (chloroform solvent)

Method: 30-250°C, 10C/min, 40mL/min N₂
30.0-250.0°C 10.00°C/min N₂, 40.0 mL/min

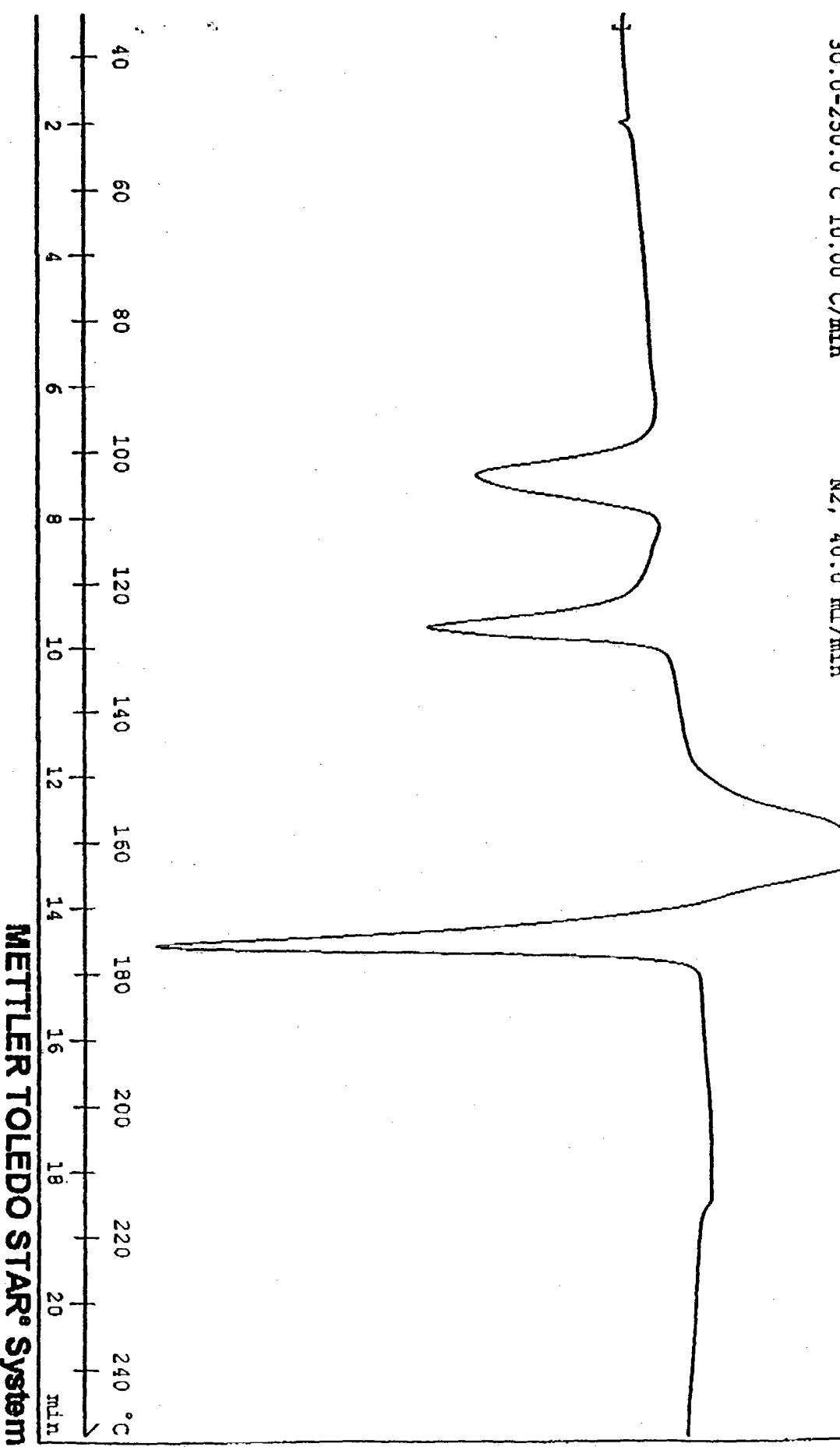
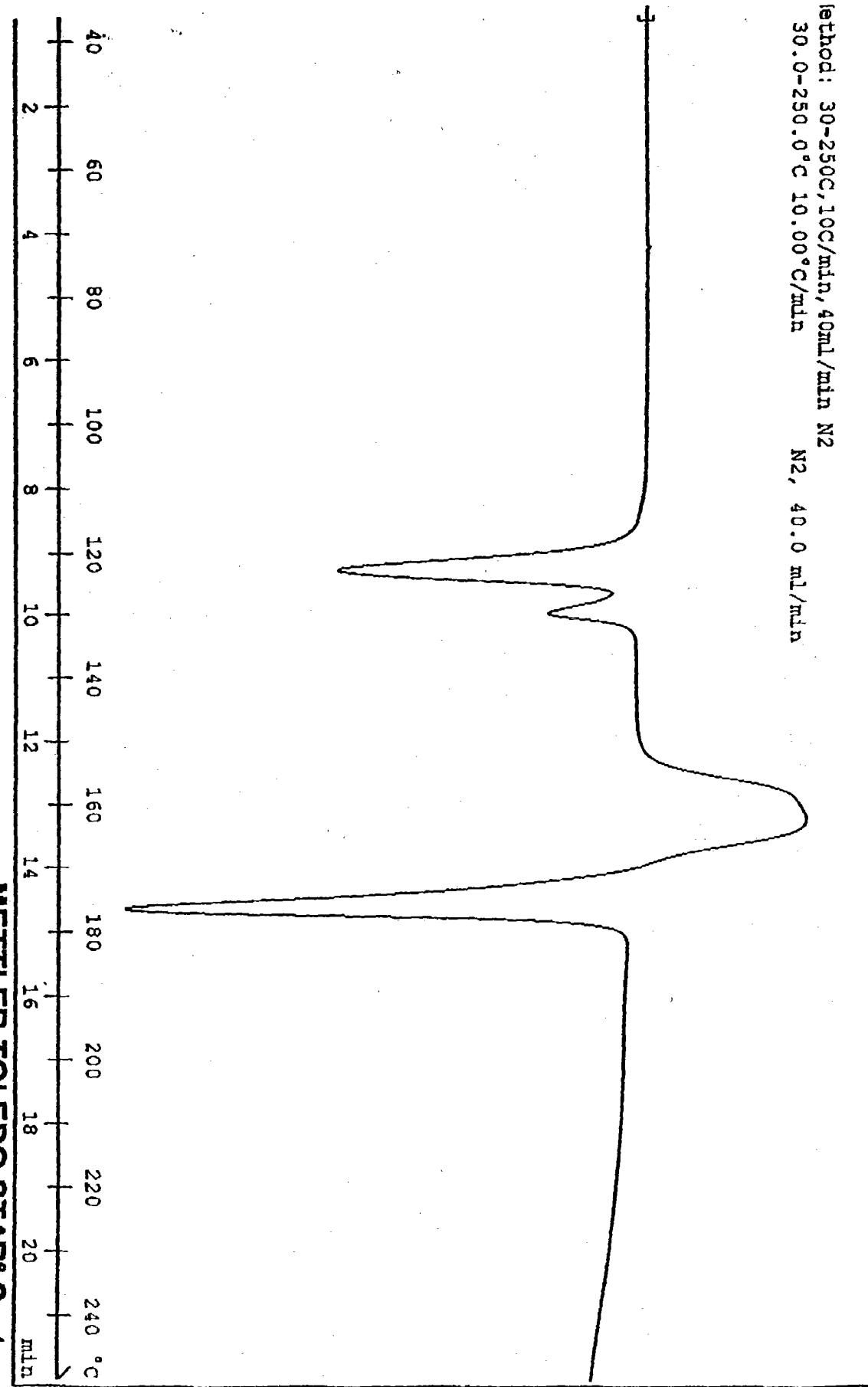


FIGURE 54
 γ (dichloromethane solvate)



METTLER TOLEDO STAR® System

Figure 27 - Nørglinde Form Z
55

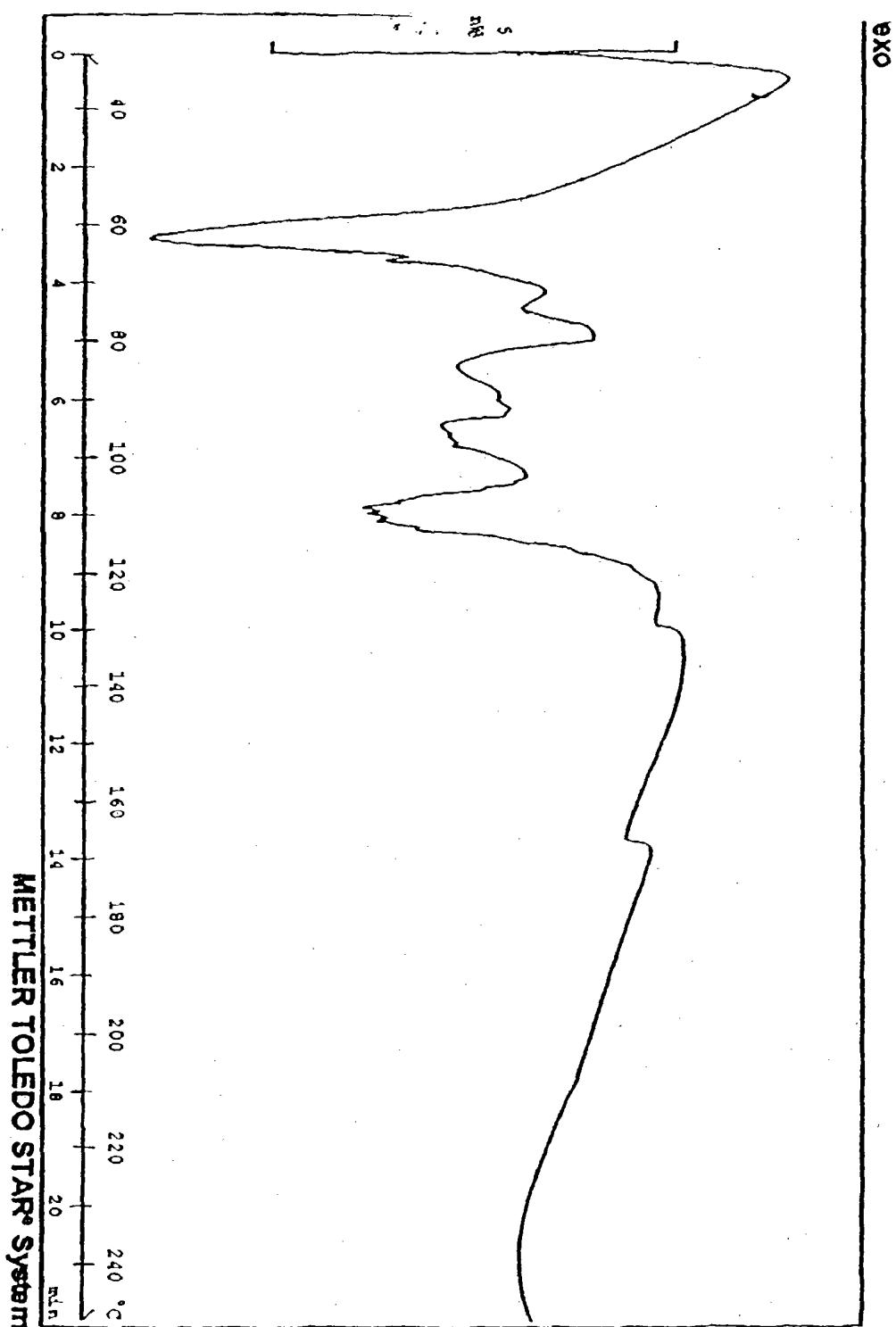


FIGURE 5-6
Form α

Method: 30-250°C, 10C/min, 40mL/min N₂
30.0-250.0°C 10.00°C/min N₂, 40.0 mL/min

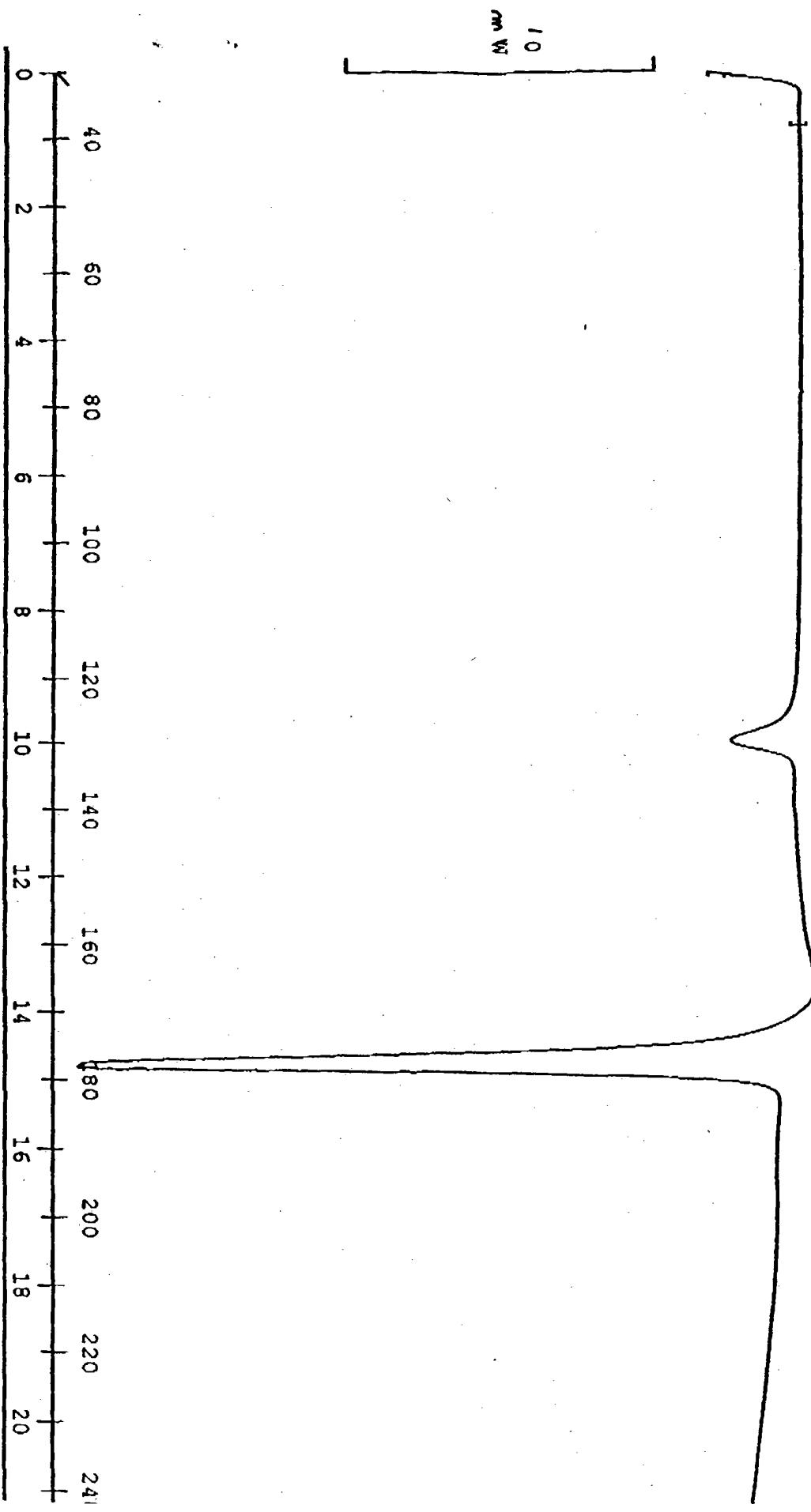


Figure 57
Form Beta

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min N2, 40.0 mL/min

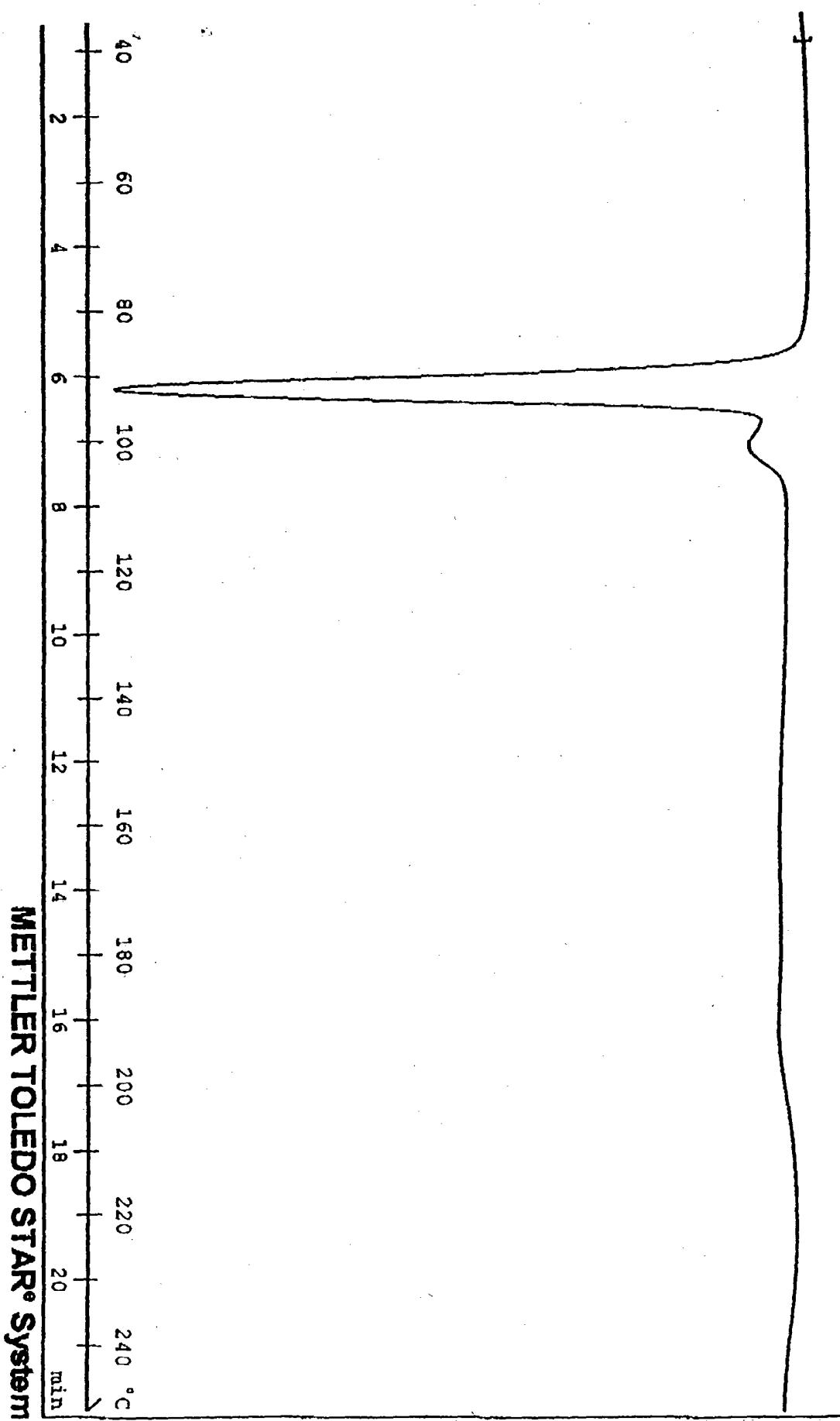
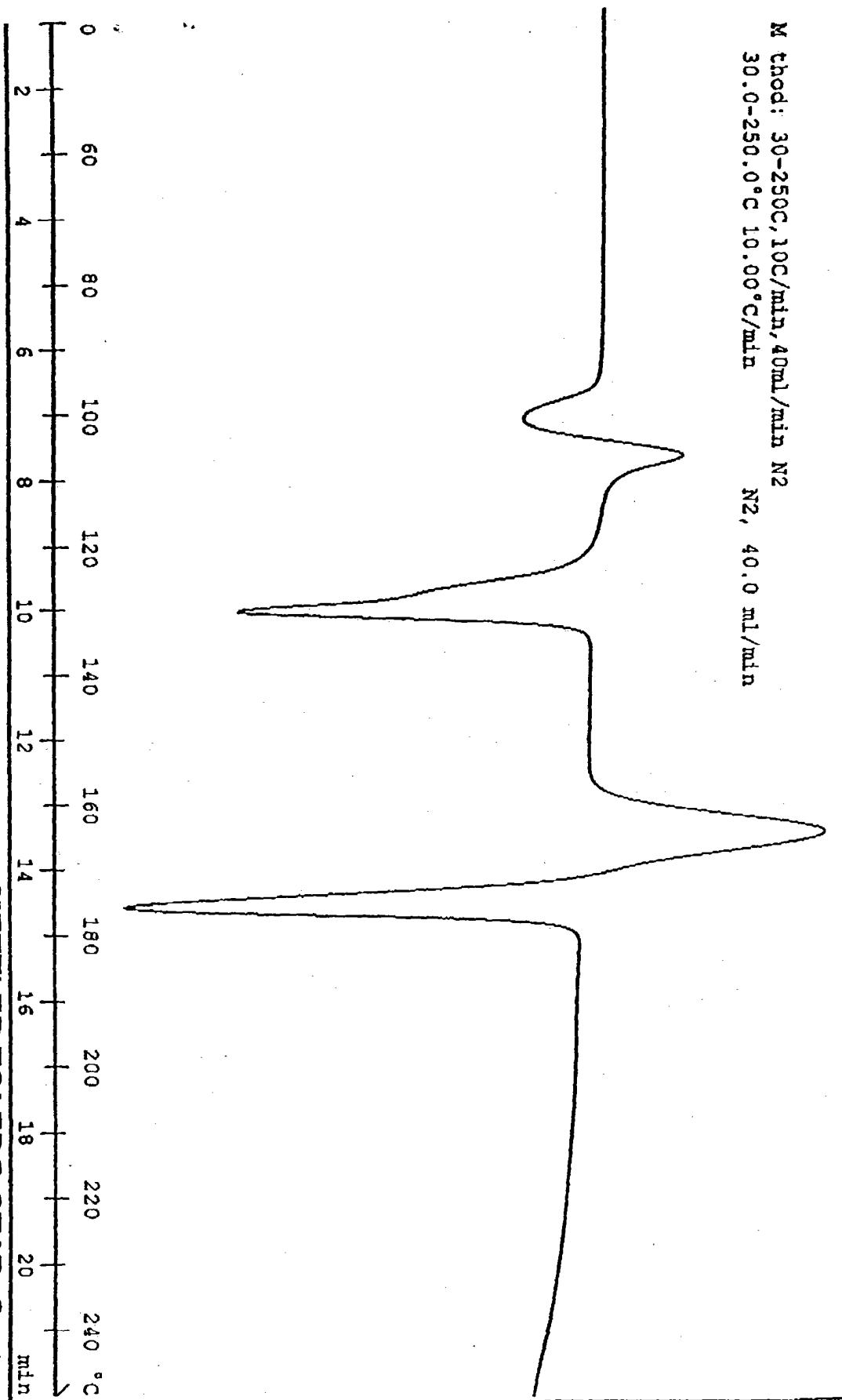


FIGURE 55-58

Form Delta

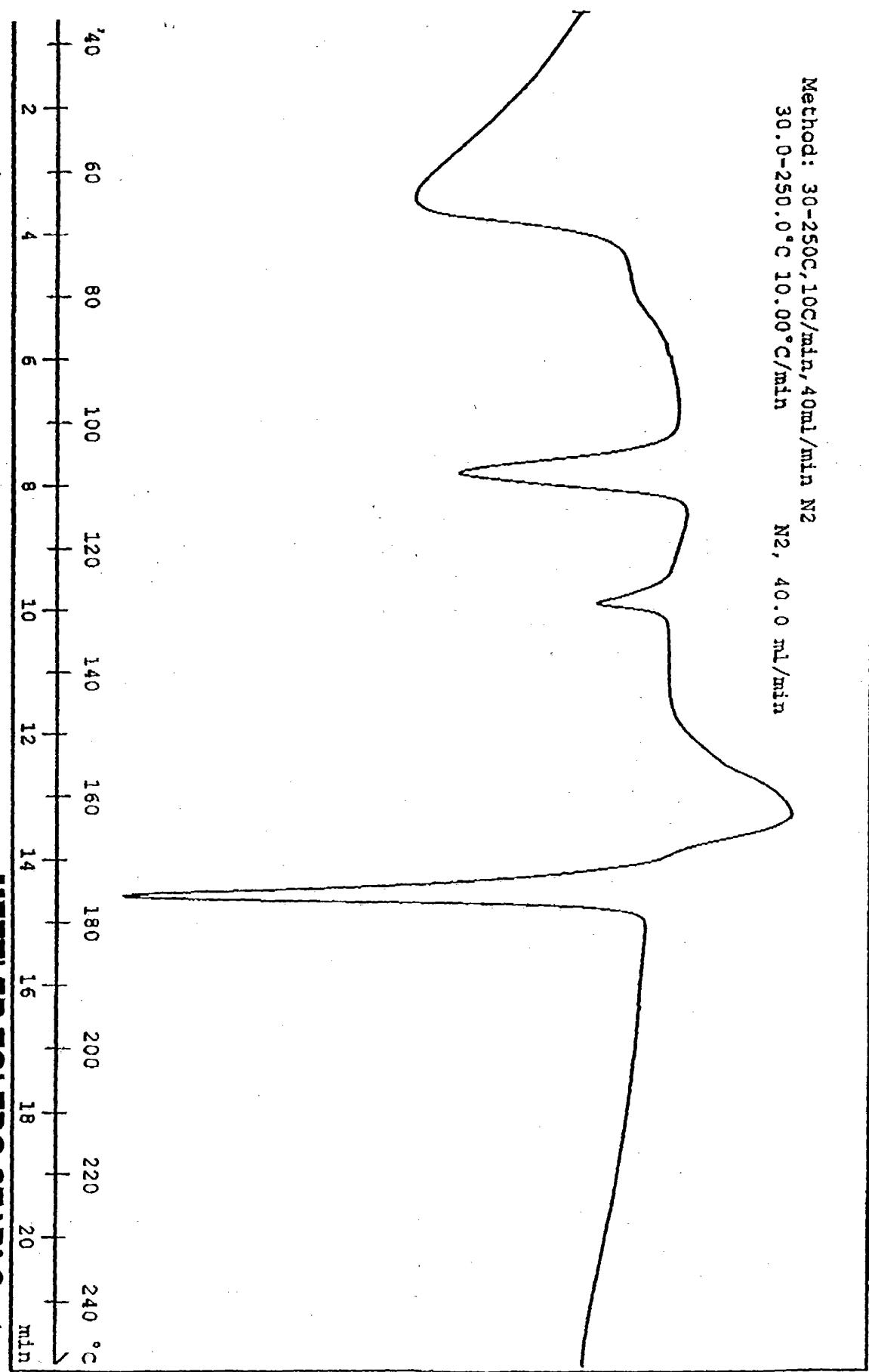
Method: 30-250°C, 10°C/min, 40mL/min N₂
30.0-250.0°C 10.00 °C/min
N₂, 40.0 mL/min



- Delta

METTLER TOLEDO STAR System

Form Epsilon FIGURE 59



METTLER TOLEDO STAR® System

FIGURE 47⁶⁰

Form  Gamma

Method: 30-250C, 10C/min, 40mL/min N₂
30.0-250.0°C 10.00°C/min N₂, 40.0 mL/min

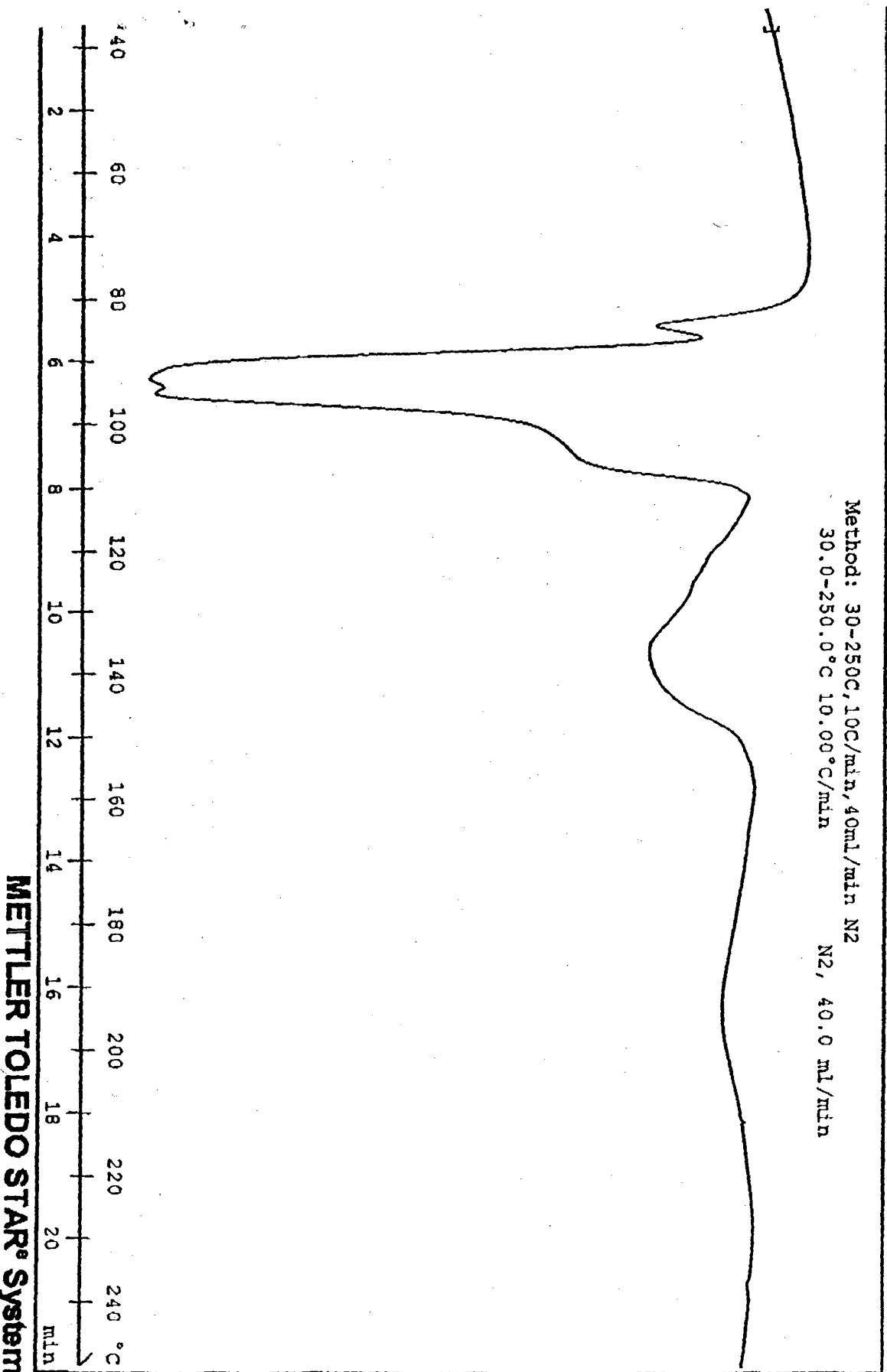


FIGURE 58 61

Form Sigma

exo

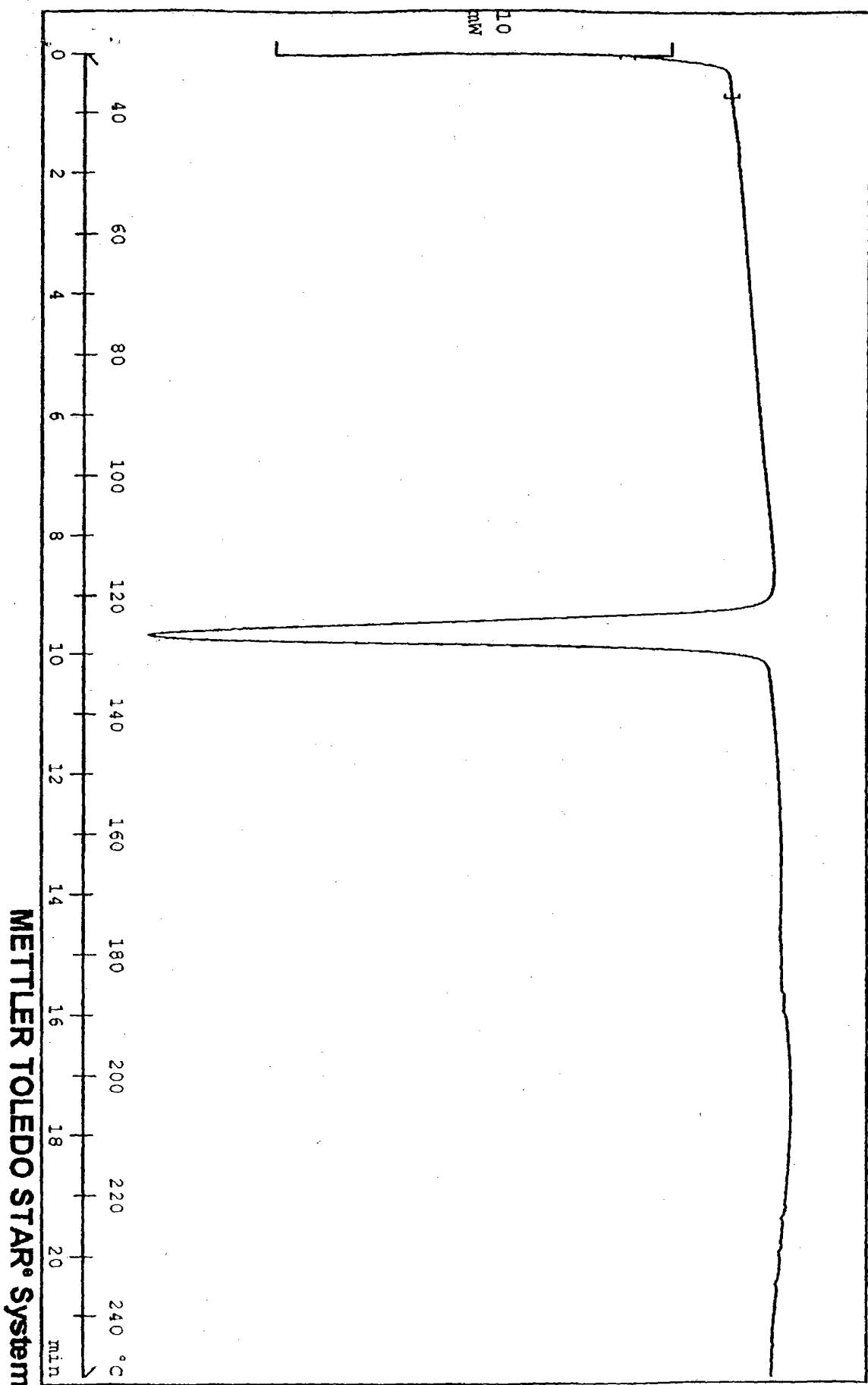


FIGURE 62

Form Theta

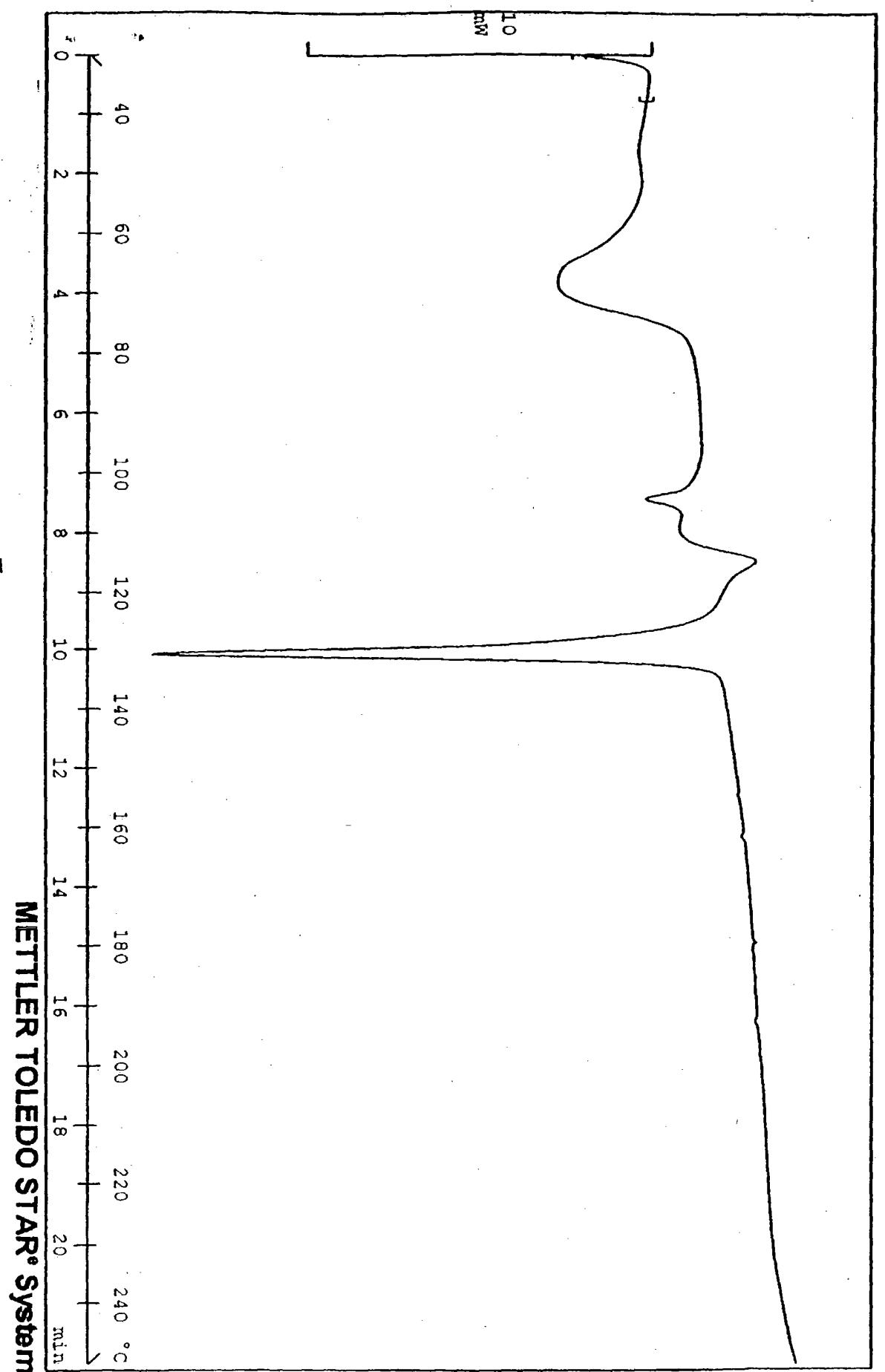


Figure 63

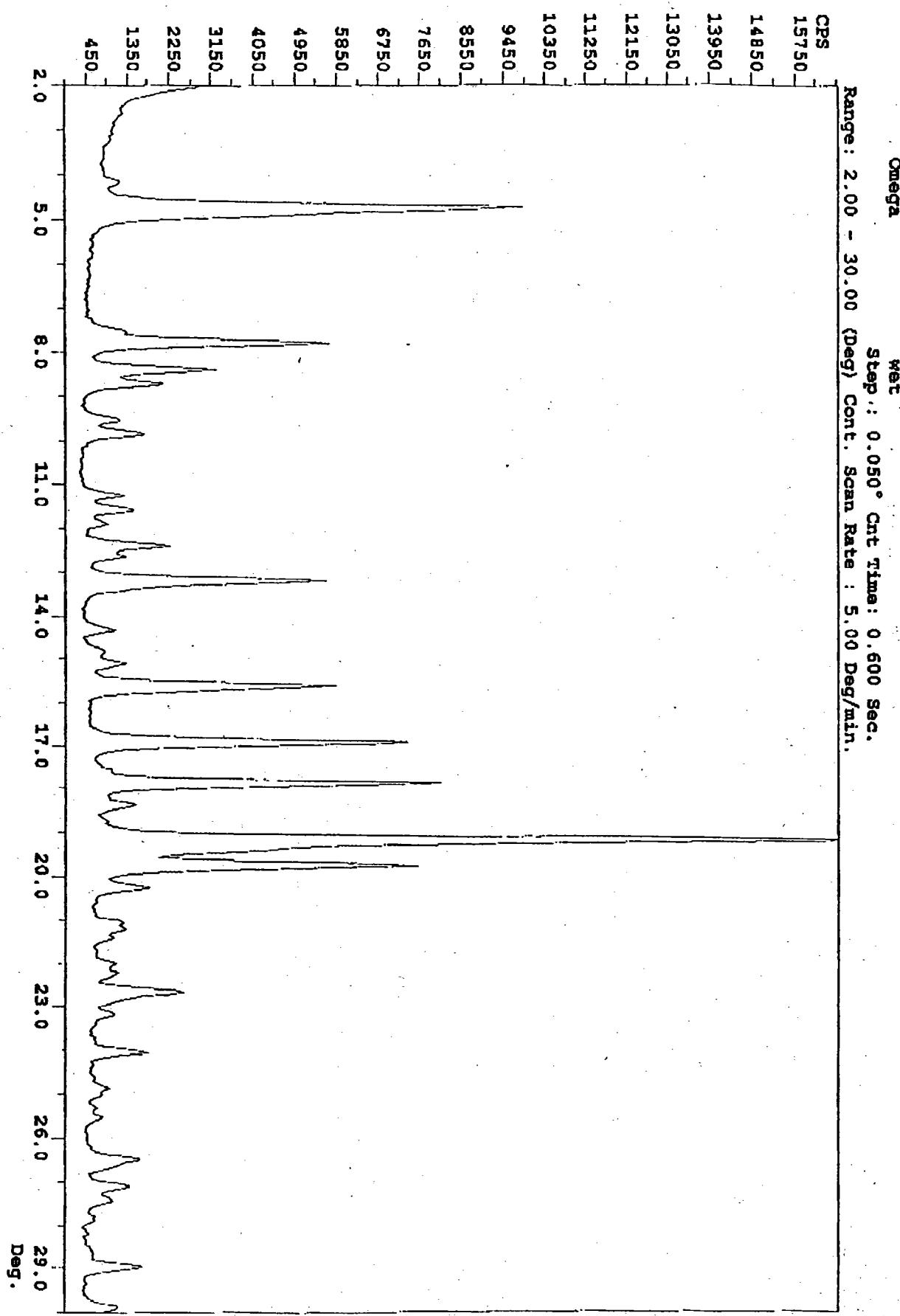


Figure 64

Comparison between the impurity profile of Nateglinide crystallized in IPA-H₂O and Nateglinide crystallized in Methanol-H₂O

Sample No	Solvent	Impurity profile by RRT [% w/w]								
		D-PA (0.23)	(0.25)	(0.46)	(0.80)	Ipcha (0.89)	Dimer (1.38)	Methyl Ester (1.51)	(1.76)	Isopropyl Ester (2.3)
RL-2155/1	Methanol-H ₂ O	<0.01		0.02	<0.01	0.03	0.02	2.91	0.04	
RL-2163/4	IPA-H ₂ O	<0.01		0.04		0.02	0.02	0.01	0.03	0.02

Note: D-PA means D-Phenyl Alanine

Ipcha means Iso propyl cyclohexyl carboxylic acid

Both are the starting materials of the product

(-)-N-[*trans*-4-isopropyl cyclohexane]carbonyl-D-phenylalanine